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In response to emphasis on patient safety following publication, in November 1999, of the Institute of Medicine's report "To Err Is Human," U.S. Army Medical Command (MEDCOM) established a Patient Safety Program for the Army Medical Department (AMEDD). MEDCOM Regulation 40-41 directs each Medical Treatment Facility to implement a Patient Safety Program dedicated to avoiding harm and enhancing patient safety. As part of a comprehensive strategy to improve safety by first assessing the magnitude of the problem, MEDCOM administered a "Patient Safety Climate Survey" to staff of all U.S. Army Military Treatment Facilities (MTFs) in August/September 2001. Nineteen Likert scale items and one open-ended question assessed perceptions about three conceptual components of an effective patient safety program: willingness to report errors, organizational problem-solving process, and perceptions about leadership concern for patient safety. The purpose of this study was to analyze the 10,768 responses to assess the corporate climate, identify respondents' perceptions of barriers to reporting errors, prioritize safety issues identified, and make recommendations for improving patient safety throughout the AMEDD. Although a "culture of blame" exists in Army MTFs, respondents perceive that leadership is concerned about patient safety and that problem solving processes to reduce medical error are being implemented.

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Analysis of the MEDCOM Patient Safety Climate Survey:

Implications for Implementation of the AMEDD Patient Safety Program

A Graduate Management Project

Submitted to the Faculty of

U.S. Army-Baylor University

by

LTC JoAnn S. Doleman, AN

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Abstract

In response to emphasis on patient safety following publication in November 1999, of the Institute of Medicine's report "To Err Is Human," U.S. Army Medical Command (MEDCOM) established a Patient Safety Program for the Army Medical Department (AMEDD). MEDCOM Regulation 40-41 directs each medical treatment facility to implement a Patient Safety Program dedicated to avoiding harm and enhancing patient safety. As part of a comprehensive strategy to improve safety by first assessing the magnitude of the problem, MEDCOM administered a "Patient Safety Climate Survey" to staff of all U.S. Army Military Treatment Facilities (MTFs) in August/September 2001. Nineteen Likert scale items and one open-ended question assessed perceptions about three conceptual components of an effective patient safety program: willingness to report errors, organizational problem-solving processes, and perceptions about leadership concern for patient safety. The purpose of this study was to analyze the 10,768 responses to assess the corporate climate, identify respondents' perceptions of barriers to reporting errors, prioritize safety issues identified, and make recommendations for improving patient safety throughout the AMEDD. Although a "culture of blame" exists in Army MTFs, respondents perceive that leadership is concerned about patient safety and that problem solving processes to reduce medical error are being implemented.

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Analysis of the MEDCOM Patient Safety Climate Survey: Implications for Implementation of the AMEDD Patient Safety Program

Introduction

Conditions Which Prompted the Study

Publication in November 1999, of the Institute of Medicine's (IOM) report "To Err Is Human: Building a Safer Health System", brought medical errors to the forefront of public attention. Established by former-President Clinton, the Quality Interagency Coordination Task Force (QuIC), an umbrella organization designated to coordinate Administration efforts to improve health care quality, evaluated the recommendations of the IOM report and provided an action plan to implement initiatives to help prevent medical errors throughout the Nation's health care delivery system (Quality Interagency Coordination Task Force, 2000). The QuIC believes that research is necessary to understand the magnitude of the problem, its causes, and its burden on people and the health care system. Without the evidence base provided by substantial research, efforts to reduce errors may not be fully effective and patient safety may be further compromised. A National Summit was held on September 11, 2000 to set priorities for a national research agenda to address the issue of medical errors and patient safety. In his opening remarks, John Eisenberg, M.D., M.B.A. emphasized that reducing medical errors and improving patient safety requires a long- term investment and international commitment (QuIC National Summit on Medical Errors and Patient Safety Research, 2001).

In July 2001, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) implemented new patient safety standards emphasizing the role of strong organizational leadership in developing a culture of safety. Such a culture encourages internal reporting of medical errors and near misses, and the prospective analysis and redesign of

potentially vulnerable patient care systems. The standards stress the organization's responsibility to inform patients about the outcomes of care, including unanticipated outcomes (Joint Commission on Accreditation of Healthcare Organizations, 2001).

Immediately following the release of the IOM report on medical errors, President Clinton issued an Executive Order directing the Department of Defense to evaluate current error reduction methods and to establish a program to reduce medical errors in the Military Health System (MHS) (Appendix A). The Assistant Secretary of Defense (Health Affairs) formed a Patient Safety Working Group with representation from Health Affairs, TriCare Management Agency, Army, Navy, Air Force, the *U.S. Uniformed Health Services*, the Air Force Institute of Pathology, and the Veterans Health Administration. The Patient Safety Working Group completed a draft Department of Defense Instruction (DoDI) in April 2000 that establishes a Patient Safety Program for the identification and central reporting of actual and potential medical systems problems so that actions to improve patient safety throughout the MHS can be implemented. This Instruction was published in final form on August 16, 2001 (Appendix B). Pilot testing of the program at five Military Treatment Facilities was completed in March 2001, with full deployment of the program throughout the MHS scheduled to follow evaluation and implementation of recommended changes (Powers, 2000).

On July 11, 2001, U.S. Army Medical Command (USAMEDCOM) released a draft publication establishing a Patient Safety Program for the Army Medical Department (AMEDD). The AMEDD Center of Excellence at USAMEDCOM will facilitate communication and coordination to develop a corporate patient safety system and process improvement initiatives. It establishes procedures for each military medical treatment facility to implement a Patient Safety Program (PSP), dedicated to avoiding patient harm and enhancing patient safety (U.S. Army

Medical Command, 2001). A Patient Safety Program (PSP) as defined by USAMEDCOM, will have the following components: 1) a designated Patient Safety Manager, 2) allocated resources to sustain a comprehensive, integrated PSP, 3) strategies to motivate and facilitate staff identification and reporting of patient safety events and "near misses", 4) designated committee membership responsible for oversight of all patient safety activities, 5) education of all staff on patient safety responsibilities, effective communication, and teamwork, 6) acknowledgment of and timely feedback to staff who submit patient safety reports, 7) patient notification, by a qualified health care provider, of an event that results in patient harm, 8) support for staff involved in a sentinel event to facilitate their professional and emotional reconciliation of the event, and 9) education of MTF beneficiaries regarding their responsibilities in the identification of patient safety issues (United States Army Medical Command, 2001). MEDCOM Regulation 40-41: The Patient Safety Program, was finalized on January 14, 2001 (Appendix C).

As part of a comprehensive strategy to improve patient safety by first assessing the magnitude of the problem, USAMEDCOM administered a Patient Safety Climate Survey to staff of all U.S. Army Military Treatment Facilities (MTFs) in August/September 2001, to include medical centers (MEDCEN), community hospitals (MEDDAC), and free standing ambulatory clinics. Staff willingness to report errors, assessment of problem solving processes, and perceptions about leaders' concerns for patient safety were components of the survey. Initial survey results serve as a baseline assessment of the patient safety climate at each MTF. Selected personnel from each MTF attended a Patient Safety Training Program conducted at USAMEDCOM and then assisted in implementation of a Patient Safety Program at their respective MTFs. Twelve to eighteen months from the date that personnel attend patient safety training, the patient safety climate will again be assessed at each MTF, providing a measure of

the organization's success in creating a climate conducive to identifying errors, evaluating contributing causes, and improving patient safety (L.M. Connelly, personal communication, July 15, 2001).

Statement of the Problem

USAMEDCOM mandated the implementation of a Patient Safety Program at all Army MTFs. Success of a Patient Safety Program is dependent on an organizational climate that encourages the reporting of medical errors and near misses, and utilizes data in a non-punitive manner to proactively design a safer environment for patients. This study will evaluate the patient safety climate of the AMEDD as determined by analysis of the MEDCOM Patient Safety Climate Survey.

Literature Review

Definition of Terms

Attempting to standardize terminology, the IOM adopted the following definition: "an error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim" (QuIC, p. 29, 2000). The QuIC expanded the IOM definition to include the phrase: "Errors can include problems in practice, products, procedure, and systems" (QuIC, p. 30, 2000)

An adverse event (as defined by Lucien Leape and cited in QuIC, 2000) is an injury caused by medical management that resulted in measurable disability to the patient.

A medical error is an adverse event that is preventable with the current state of medical knowledge (QuIC, 2000).

Patient safety applies to those initiatives designed to prevent adverse outcomes from medical errors (QuIC, 2000).

A near miss, or close call, is a situation or event that might have resulted in harm to a patient, however, either by chance, or through timely intervention, did not (QuIC, 2000).

Organizational culture is defined as the underlying assumptions and beliefs shared by members of the organization and that operate unconsciously (Schein, 1991).

Understanding Medical Errors

As early as the 1960s, there were reports that patients were being harmed by the medical care intended to help them (QuIC Report, 2000), however, it was not until release of the Institute of Medicine's report "To Err is Human", that the magnitude of the problem was brought to the attention of the American public. In November 1999, the Institute of Medicine (IOM) reported that 44,000 to 98,000 patients in U.S. hospitals die each year because of avoidable medical errors. The IOM estimated the total costs associated with medical errors to be as high as $29 billion annually. These costs represent lost income, disability, and the expense of additional health care. The IOM report exposed a pattern of miscommunication and medical errors even in those hospitals whose care was ranked the best in the world (Kohn, Corrigan, & Donaldson, 1999). When the IOM report was published, some argued that the numbers were exaggerated. The IOM arrived at the figure 98,000 by generalizing the findings of a 1991 study. In that study, one year's worth of medical practice adverse events in New York were independently reviewed by two physicians per case who were asked to determine whether the adverse event was caused by an error. Using two independent judgments of each case, 58 % of the events were found to have resulted from medical error. When this 58 % was generalized to the country as a whole, 98,000 deaths annually, attributable to medical error, was the result. In fact, this number is probably an underestimate because it relied on information in medical records, and much information of this kind is not reported in medical records. Additionally, this estimate is based

on hospital injuries only. There are no measures of errors, injuries, and deaths for ambulatory surgical procedures and outpatient care. The 98,000 figure also doesn't include the 10 % error rate for medication prescriptions, most of which are written outside the hospital (Buerhaus, 2001). The magnitude of the problem caught the attention of the media, the American public, and the health care industry and has become the focus of major initiatives to reduce medical errors and increase patient safety.

Research sponsored by the Agency for Health Care Policy and Research indicated that the rate of health care errors is higher than the error rate in other industries. Like other industries, health care relies on systems of interactions between humans and technology to perform functions that lead to outcomes. In Demanding Medical Excellence, Millenson states that health care is unique in its complexity and many medical errors are attributable to the fact that the knowledge base needed to safely and effectively deliver care exceeds the capacity of the human brain (QuIC, 2000).

The IOM reports that the majority of medical errors do not occur because of lack of education or competence of providers, but because of poor systems design and organizational factors. For example, health care workers may be required to work additional shifts, although it is recognized that overwork and fatigue contribute to decreased alertness and concentration. The organization may not invest adequately in information technology to support vital decision-making processes. The fragmented nature of the health care industry and poor communication between departments and specialties within an organization contribute to medical errors. Health care is delivered through a series of complex processes whose multiple steps decrease the likelihood of any task being perfectly performed. Finally, health care providers work in an environment where one error, whether preventable or not, may mean the end of a career (QuIC,

2000). When systems fail, industry leaders advocate replacing the traditional blame and punishment approach with critical analysis that will encourage process redesign that supports care givers, not sets them up for failure (Pate & Stajer, 2001).

Reporting of Medical Errors

The discovery of medical errors occurs through a variety of means. Retrospective morbidity and mortality reports, malpractice data claims, retrospective chart review, computerized surveillance, and incident reporting systems all may provide for the capture of data on errors and adverse events in medicine. Incident reporting provides a relatively inexpensive methodology and may target events in three basic categories: adverse events, events that were unintended but resulted in no harm to the patient, and near misses. Few research studies have analyzed the benefits of incident reporting, and none have established the value of incident reporting on patient safety outcomes, however, because incident reporting has been of benefit in other high-risk industries, its use in health care appears to be growing in importance (Wald & Shojania, 2001). Because medical errors are being increasingly recognized as the result of flawed systems, to pinpoint the weaknesses in these systems one must first know what errors are occurring. This is difficult because the majority of errors are not reported. The QuIC states that most reporting systems currently in use have little enforcement authority to ensure consistent and complete reporting, resulting in unreliable measurements of the extent of health care error. Citing studies by Barach and Small and by Leape, Grube states estimated underreporting of adverse events to range from 50% to 96% annually (Grube, 2001).

Barriers to Reporting Health Care Errors

The litigious environment in the U.S. makes health care professionals who are at risk of liability reluctant to report adverse events, particularly if the event did not result in permanent injury or death. Because near misses occur more frequently than actual adverse events, not capturing these incidents reduces the chance of learning about patterns of errors and their future prevention (Grube, 2001).

A second barrier to reporting medical errors is the perception on the part of its personnel that an organization is unlikely to take action as the result of a report. Because reporting systems are an additional burdensome task on an already overworked staff, and lack of feedback to the reporter may foster the perception that no corrective action was taken, personnel involved in or witnessing a medical error may have decreased motivation to report the event (Grube, 2001).

The focus of this study is on the traditional health care culture of naming, blaming and shaming as a response to medical errors. Traditionally, the analysis of adverse events has focused on the individual, not the system. This inclination to blame individuals results from hindsight bias, the tendency to perceive a problem as much more simplified when in possession of all the facts and the outcomes. Blame discourages incident reporting and is a barrier to problem solving and process improvement. Disclosure of adverse events has traditionally exposed organizations and practitioners to financial penalties, punitive actions against accreditation or licensure, and legal and public scrutiny (Institute for Safe Medication Practices, 2000). The health care culture of blame is perpetuated in medical school where physicians, as part of the educational process, learn from errors and being blamed for them. Later, under the guise of peer review, physicians who expect perfection in themselves and their peers, tend to lay blame when expectations are not met. Nurses and other health care professionals are subject to

severe and virtually automatic discipline when errors are detected (Pate & Stajer, 2001). The solution to an adverse event lies not in firing the individual involved, but in allowing the individual to participate in the root cause analysis to examine the organizational systems that contributed to the error (Kobs, 1999). Members of a team formed to analyze a medical error must be taught to recognize and acknowledge their blaming behavior. Blame is a natural reaction to a disturbing event. After accommodating team members' emotional response to perceived performance error, the facilitator assists them to move beyond blame to identification of the error's root cause. The opportunity to learn from errors is more valuable than disciplining the individual involved, however, managers may have difficulty accepting this paradigm shift (Pate & Stajer, 2001).

American society, too, has contributed to the health care culture of perfection and blame. Rapid technological advancement in the field of medicine has given society the impression that perfection in health care is attainable. Health care is an inherently risky profession and to expect its delivery to be error free is unrealistic. Efforts to provide the public with a realistic picture of health care professionals and the context of the health care environment is warranted (Grube, 2001). The title of its report, "To Err is Human", clearly indicates that the IOM recognizes that humans are fallible. Human error is inevitable and occurs because people cannot consistently outperform the unsafe systems that constrain them. Recognition of this fact contributes to a lessened tendency to blame individuals, a focus on process oriented event analysis, and error reduction efforts targeted at systems rather than individuals (Institute for Safe Medication Practices, 2000).

Changing the culture of blame to a culture that encourages the reporting of errors and close calls for the sole purpose of learning from and preventing future mistakes will not occur

overnight. Dr. James Bagian, director of the Veterans Health Affairs (VHA) National Center for Patient Safety (NCPS), says it takes at least five to seven years to change an organization's culture. He cites the greatest improvement in the VHA system as "changing individual attitudes." Personnel in a punitive environment learn to "stay out of the line of fire." When leadership demonstrates its commitment to patient safety by using reports of adverse events and close calls to study and improve processes and systems, individuals are encouraged to participate in patient safety initiatives and willingly report medical errors (Mears & White, 2002).

Creating Effective Error-Reporting Systems

The actual prevalence of events appropriate for reporting is impossible to accurately estimate. The incident reporting systems currently in use in most hospitals fail to capture the majority of medical errors and near misses. Applicable literature cites the chronic underreporting of medical errors and attributes this to cultural and environmental factors. Rather than being indicative of an unsafe organization, an increase in incident reporting rates may reflect a shift in organizational culture to the increased acceptance of quality improvement initiatives (Wald & Shojania, 2001).

Reporting errors is essential to reducing them and, thus, to improving patient safety. Components of an effective reporting system include top leadership support, clearly stated goals, confidential and anonymous reporting, and feedback on corrective actions taken (Grube, 2000). The true causes of adverse events are management decisions that affect resources, process design, and organizational culture. The efficacy of an organization's functions either support or detract from a provider's chance of success (Pate & Stajer, 2000). For error reporting systems to succeed, top leadership must incorporate error reduction and accountability, rather than blame, as core values of the organization. Leadership support of a non-punitive system that encourages the

reporting of medical errors and near misses will enable the building of a large performance indicator database that can be analyzed for trends and opportunities for effective system improvements (Levy & Lancaster, 2001).

Leaders must communicate assurances that reported data are to be used to improve patient safety, not for punitive purposes. Patient safety program policies should be included in training programs to ensure appropriate reporting of patient safety issues, and to provide clear guidelines about how to report and who should receive the report (Grube, 2001).

Evidence suggests that systems that are confidential increase the number of events reported. For organizations unable to provide voluntary and anonymous systems of reporting, addition of alternative reporting systems such as suggestion boxes or near miss boxes may increase the number of reports (Grube, 2001).

Finally, reporting systems must do more than track and trend the number of errors in order to reduce them. Systematic investigation of adverse events should include a root cause analysis. Timely feedback on what actions were taken reinforce to the reporter leadership's commitment to improving patient safety (Grube, 2001).

The IOM recommends the establishment of a nationwide error reporting system with both mandatory and voluntary components. The mandatory reporting system would initially be required of hospitals, and eventually include other institutions and ambulatory care systems. The mandatory system would provide the means to collect data about adverse events that result in death or serious injury. Voluntary reporting systems can identify near misses, potential precursors to error that can identify process failure. Patient safety programs require reporting systems that hold organizations responsible for the delivery of high quality care and provide decision makers with the information to improve patient safety (QuIC, 2000).

In support of the IOM goal of reducing the number of medical errors by 50 % over five years, QuIC agencies advocated implementing a system of public accountability, developing an extensive knowledge base about medical errors, and changing the culture of health care organizations to promote the recognition and reporting of errors (QuIC, 2000).

Purpose

The purpose of this study is to analyze responses to the MEDCOM Patient Safety Climate Survey to: 1) assess the corporate culture and climate, 2) identify respondents' perceptions of barriers to reporting medical errors, 3) prioritize patient safety issues identified by the respondents, and 4) make recommendations for improving patient safety throughout the AMEDD.

Methods and Procedures

In support of the national and Military Health System (MHS) directive to improve patient safety, USAMEDCOM developed a comprehensive corporate Patient Safety Program to assist MTFs in their implementation of this program. Three initiatives were identified as key to successful implementation of Patient Safety Programs at the MTFs: 1) the AMEDD Patient Safety Climate Survey, 2) the AMEDD TapRoot Program, and 3) the AMEDD Patient Safety Training Program. A baseline multidisciplinary assessment of culture/climate prior to any change effort is essential to success in any work redesign (Jones, DeBaca, & Yarbrough, 1997). This study consists of qualitative research designed to analyze the responses to the AMEDD Patient Safety Climate Survey, make inferences about the corporate culture and climate that affect implementation of the Patient Safety Program, prioritize identified safety issues, and make recommendations to encourage and facilitate the reporting of medical errors.

The AMEDD Patient Safety Climate Survey (Appendix D) was administered electronically to all Army MTFs from mid-August to the end of September 2001. Facilities were asked to provide all personnel with access to a computer with web capability and privacy to complete the survey. To ensure anonymity, respondents were asked to identify only their MTF and their position, i.e. staff nurse, physician, pharmacy technician, administrator, etc. Demographic data were assessed for the purpose of reporting to MTFs that respondents represent the spectrum of staff at each MTF.

The final version of the survey consisted of the two demographic questions identified above, 19 Likert scale items, and one open-ended item asking respondents to identify the number one safety issue in their facility. A four-point Likert scale, with possible responses of 1) strongly disagree, 2) disagree, 3) agree, and 4) strongly agree, was used. A four-point scale was chosen to force respondents to agree or disagree with each item. Thus, respondents who did not feel strongly about an issue and might have chosen a neutral position if offered, were forced to indicate the direction toward which they leaned (Converse & Presser, 1986). The 20th item asked, "What is your perception of the number one Patient Safety issue at your facility?" and a textbox limiting the response to that question to 1000 characters was provided. Surveys were submitted online to USAMEDCOM for aggregation and analysis centrally. The survey falls under quality improvement efforts and was exempt by the Clinical Investigation Regulatory Office from the requirement for Internal Review Board (IRB) approval. The results of each organizational assessment were provided directly to the organization prior to its representatives attending the AMEDD Patient Safety Training Program (W.T. Bester, memorandum, July 13, 2001). Initial survey results served as a baseline assessment of each MTFs patient safety climate. Twelve to 18 months after selected personnel attended the AMEDD Patient Safety

Training and the organization has fully implemented its Patient Safety Program, MTFs will be resurveyed. Periodic survey will provide a measure of the organization's patient safety climate (L.M. Connelly, personal communication, July 15, 2001).

Investigators developed the AMEDD Patient Safety Climate Survey by reviewing pertinent literature and assessing a variety of existing tools. Because many of the tools were too long and no one tool covered the desired content, the investigators generated the specific items on the survey from a review of the literature and based on the conceptual framework of the project. Likert scale items were developed to assess perceptions about three conceptual components of an effective patient safety program: 1) staff willingness to report errors, 2) problem-solving processes within the organization, and 3) perceptions about leadership concern for patient safety.

The tool was reviewed for content validity, the extent to which the survey items provide adequate coverage of the investigative questions of the study (Cooper & Shindler, 2001), by a panel of experts on patient safety, quality, risk management, and research (Appendix E). An item with a Content Validity Index of less than one was eliminated or was reworded and reassessed. A second round of content validity was conducted. Prior to AMEDD-wide administration, internal consistency reliability was tested with 43 students at the AMEDD Center and School who had clinical backgrounds, and had recently left a Medical Treatment Facility. Cronbach's alpha was .86. When repeated on the present study, Cronbach's alpha was .90. Test-retest reliability was determined with the same group of students two weeks apart, with a correlation of .98.

Construct validity was assessed by the use of factor analysis to see if the three hypothesized theoretical constructs (staff willingness to report errors, problem-solving processes,

and perceptions about leadership concern for patient safety) would be supported. Principal component analysis with varimax rotation was used to examine the data (StatSoft, Inc. 2002). A three-factor solution was obtained but on examining the loadings, the nature of the factors was slightly different than the hypothesized construct. The items in Factor 1 related to reporting errors. The items in Factor 2 related to problem solving and several leadership items. The items in Factor 3 were a combination of negative leadership and items reflecting the "culture of blame." These factors are close to the original hypothesizing construct and make a certain, logical sense when reviewing the instrument items ((L.M. Connelly, personal communication, February 28, 2002). Construct validity was assisted by including in the introduction to the survey questionnaire operational definitions for patient safety, near miss/close call, and sentinel events, to ensure that the constructs were theoretically meaningful to those being surveyed. The focus of the tool was quality improvement assessment for practical application rather than stringent research for theoretical purposes (L.M. Connelly, personal communication, October 7, 2001).

Results

There were 11,136 responses to the survey. Automation problems resulted in some duplicate responses, which were cleaned from the database. The resulting N= 10,768 represents an estimated corporate response rate of 39 %, based on Patient Administration Systems and Biostatistics Activity (PASBA) numbers of AMEDD personnel. All MTFs in the AMEDD were represented in the responses. As previously noted, in order to ensure anonymity, position and facility were the only demographics requested of each respondent. The position demographic was ascertained by a pull-down menu containing 19 possible job categories from which respondents could select only one. Among the positions that were inadvertently omitted were Operating Room Technician and Physical Therapy Technician.

Table 1 Demographics

Demographics			
Total responses:			**10,769**
Respondents by position		**Respondents by facility**	
Administrator/Supervisor	2,083	Bassett ACH	181
Dietary Technician	45	Baynes-Jones ACH	187
Dietician	62	Blanchfield ACH	289
Lab Technician	332	Brooke AMC	437
LPN/91C	626	Darnall ACH	779
NA/91B	691	Dewitt ACH	170
Nurse Practitioner	185	Eisenhower AMC	692
Occupational Therapist	42	Evans ACH	317
Physician's Assistant	137	Fox ACH	79
Pharmacist	152	Guthrie AHC	271
Pharmacy Technician	200	Heidelberg	273
Physical Therapist	133	Ireland ACH	158
Physician	1,349	Irwin ACH	183
Psychiatric Technician	101	Japan	59
Psychologist	108	Keller ACH	236
Radiology Technician	193	Kenner AHC	77
Social Worker	227	Kimbrough AHC	203
Speech Therapist	16	Korea	113
Staff RN	1108	Landstuhl AMC	385
Other	2,979	Leonardwood ACH	260
		Lyster ACH	297
		Madigan AMC	551
		Martin ACH	193
		McDonald ACH	117
		Moncrief ACH	297
		Munson AHC	156
		Patterson AHC	27
		Raymond Bliss AHC	31
		Reynolds ACH	167
		Tripler AMC	1,174
		Vicenza	35
		Walter Reed AMC	609
		Weed ACH	118
		William Beaumont AMC	183
		Winn ACH	140
		Womack AMC	1,045
		Wuerzburg	275

"Other" was included as a position choice on the pull-down menu and encompasses MTF personnel outside the clinical arena, such as those in logistics and clerical support personnel. As can be seen in Table 1, a large number of individuals (2,979) selected this option as their position identifier. A second pull-down menu asked respondents to identify their assigned MTF. When the responses were tabulated, those from sub-clinics were rolled into the parent clinic results.

Table 2 Item Analysis

Item Analysis				
	Question	Corp	SD	
	Most people in this MTF:			
1.	are willing to report clinical errors.	3.04	.681	Agree
2.	agree that patients also play a role in preventing clinical errors.	3.25	.610	Agree
3.	*fear there will be negative consequences associated with reporting clinical errors.*	*2.50*	*.780*	*Agree*
4.	provide support for those who make unintentional clinical errors.	2.96	.666	Agree
5.	cooperate with one another to resolve patient safety issues.	3.19	.648	Agree
6.	*are not willing to admit to patients when they make an error.*	*2.37*	*.747*	*Disagree*
7.	regularly report clinical errors.	2.70	.709	Agree
8.	feel comfortable reporting unsafe patient conditions to the supervisor.	3.08	.712	Agree
9.	believe things will be done to reduce the likelihood of a clinical mishap.	3.25	.557	Agree
10.	*do not believe the organization's senior leaders place a high priority on patient safety.*	*1.96*	*.804*	*Disagree*
11.	believe most clinical errors are preventable.	3.13	.525	Agree
12.	are willing to discuss what went wrong when a sentinel event occurs.	3.10	.611	Agree
13.	*often blame others for their own mistakes.*	*2.23*	*.757*	*Disagree*
14.	are willing to report near miss/close call patient incidents.	2.74	.668	Agree
15.	believe their immediate supervisors are committed to improving patient safety.	3.10	.646	Agree
16.	*hesitate to change practice habits to improve patient safety.*	*2.14*	*.731*	*Disagree*
17.	are willing to share information about clinical errors and what caused them.	2.95	.625	Agree
18.	regularly report clinical errors whether or not the patient was harmed.	2.74	.701	Agree
19.	believe MEDCOM leadership is truly committed to improving patient care.	3.06	.658	Agree
	Average overall score	**2.95**	**.403**	

Item analysis of each question is displayed in Table 2. Each item was scored on a four-point scale from **Strongly Disagree (1), Disagree (2), Agree (3),** to **Strongly Agree (4)**. Questions 3, 6, 10, 13, and 16 are negatively worded to discourage response set, the selection of all the same responses in a column. A response to these five questions of "disagree" or "strongly disagree" would indicate perception of a climate that is non-punitive and supports the reporting of errors. The following scale can be use to evaluate item responses:
3.5-4.0 strongly agree; 2.5-3.49 agree; 1.5-2.49 disagree, and 1.0-1.45 strongly disagree.

Question 20 requested respondents to identify their perception of "the number one Patient Safety issue at your facility." Responses were limited to 1000 characters or less. There were 5,621 responses to this question. Some were succinct, one or two-word answers, such as "falls" or "medication errors." Other responses used the maximum allowable characters and enumerated several perceived patient safety issues. Some respondents answered with specific examples of patient safety incidents and others used the space provided to vent their frustrations with their co-workers, their leadership, and/or with MEDCOM. Whenever more than one patient safety issue was identified by a respondent, all issues were coded separately. Thus, the resultant number of coded responses is greater than the total number of responses to Question 20. If respondents left Question 20 blank, or wrote "no comment," the item was coded as "no response." Responses of new personnel who did not feel qualified to answer Question 20 were coded as "new personnel" and were not included in the analysis. Responses to Question 20 that were critiques of the survey instrument were also removed for later evaluation. Of the 10,768 respondents to the survey, 5,147 did not provide a response to Question 20 that could be coded as a patient safety issue. The remaining 5,621 responses, when coded, yielded 6,053 patient safety issues identified.

Table 3 Question 20: The number one patient safety issue in your facility

Number One Patient Safety Issue at Your MTF (Question 20)		
Issue	**Number Identified**	**Percent of Total**
Medication Errors	920	15.20 %
Staffing	864	14.27 %
Facility	433	7.15 %
Inexperience/ Lack of Training	362	5.98 %
Positive Comments	352	5. 82 %
Falls	294	4.86 %
Continuity of Care	267	4.41 %
Culture/ Leadership	249	4.11 %
General Comments about Patient Safety	205	3.39 %
Equipment	164	2.71 %
Infection Control	147	2.43 %
Children Unattended or Uncontrolled	146	2.41 %
Documentation Errors	145	2.40 %
Reporting of Errors	131	2.16 %
Patient Identification	127	2.10 %
Communication	126	2.08 %
Lack of Time	119	1.97 %
Patient Education	113	1.87 %
Security	105	1.73 %
Poor Attitude	101	1.67 %
Scope of Practice	89	1.47 %
Housekeeping	79	1.31 %
Accountability/ Attention to Detail	75	1.24 %
Lack of Supervision	63	1.08 %
Patient Confidentiality	49	0.81 %
Missed Diagnosis	43	0.71 %
Taskings	40	0.66 %
Transfer/ Transport of Patients	40	0.66 %
Restraints	35	0.58 %
Needle Sticks	34	0.56 %
Not Following Orders/ SOPs	26	0.43 %
Policy	24	0.40 %
Stress	24	0.40 %
Specific to Facility	16	0.26 %
Total	6053	100.00 %

A sub-sample of the comments was initially coded by one researcher and a Code Book (Appendix F) was developed with code names, abbreviations, and definitions. Coding of the responses to Question 20 was accomplished by two individuals (one of whom is the author of

this GMP) reading the responses and categorizing them according to 55 codes that evolved to accommodate the variety of responses. After the initial coding, several categories were found to be closely related or to overlap, so these were combined into a single code for those responses. Thirty-five codes emerged from this consolidation of responses and a second version of the Code Book was developed (Appendix G). Inter-rater reliability (IRR) was verified by another person independently coding a random sample of 10 % of the responses with 98 % agreement of codes. Results of the coding are in Table 3.

Discussion

Analysis of the AMEDD Patient Safety Climate Survey reveals that a "culture of blame" exists in Army Medical Treatment Facilities, consistent with the literature regarding health care organizations in general. Likert scale items were developed to assess perceptions about three conceptual components of an effective patient safety program: 1) staff willingness to report errors, 2) problem-solving processes within the organization, and 3) perceptions about leadership concern for patient safety.

Analysis of Perceptions from Likert Scale Items

Staff Willingness to Report Errors

Questions 1, 3, 7, 8, 14, and 18 assess respondents' perceptions about staff willingness to report medical errors and near miss incidents. Scores for these items are in the positive range, indicating that respondents judge their co-workers to be willing to report when errors are made that did, or might have, resulted in patient harm. However, as indicted by a positive score for item three, respondents perceive that most people in their MTF fear that there may be negative consequences associated with the reporting of medical errors.

Responses to Question 20 support the perception of a culture of blame across the AMEDD. Of the total respondents, 248 labeled their organization's culture as the primary patient safety issue. An additional 131 respondents listed the lack of error reporting as the number one patient safety issue in their organization. The following comments are representative of responses to Question 20 in which culture and leadership were identified as the primary patient safety issue. "In an Army that is geared toward zero defects, finger pointing and buck passing is going to be the obvious result. Trepidation about reporting errors is understandably quite high." "Areas that could be improved would be more support for those making unintentional clinical errors. Some supervisors are quick to place blame and accuse staff of negligence when they had made honest mistakes." "Providers have the impression that the system will try to 'fix the provider', rather than fixing the system." "Due to the punitive environment in MEDCOM most clinicians are not willing to report errors for fear of loss of clinical privileges, etc." "#1- the traditional fear that the individual will take the blame even though the system might be the problem." "This facility is very critical of errors or untoward events that may reflect negatively on the command." "A climate that fosters the 'no fault' reporting of errors does not exist."

Within the "reporting of errors" category respondents cite difficulties with the reporting process. Several indicate that they do not know how or to whom they should report errors. Others are put off by the volume of paperwork required to report an incident. Evident throughout the responses is the realization that errors must be reported so that organizations can learn from their mistakes and implement measures to reduce the likelihood of future errors.

Problem Solving Processes

Questions 2, 5, 11, 12, 14, 16, and 17, concerning problem-solving processes that can reduce medical error, all scored in the positive range. Respondents believe that most clinical errors are preventable and that the patient also bears some responsibility in preventing clinical errors from occurring. They perceive that in their organization, people feel comfortable reporting unsafe conditions to supervisors, cooperate with one another to resolve patient safety issues, and are willing to change practice habits to improve patient safety. Although respondents agree (score 3.19) with the statement "most people in this MTF cooperate with one another to resolve patient safety issues," 126 cited lack of communication among health care providers or between patients and providers as a primary safety issue. "The number one patient safety concern in this hospital is lack of communication between services concerning patient issues." "Poor communication between practitioner and patient about what is to be done, how it will be done, and the expected results." A MEDCEN respondent sums it up: "Communication starting with MD to MD, MD to nurse, nurse to aide, etc., etc., etc. Combine the lack of effective communication with limited staff and this leaves room for an increase in patient falls, med. errors, extraneous studies, and possible untoward events."

There were 352 positive comments about patient safety, which represents 5.82 % of all responses. Respondents illustrated that problem solving processes are in place at their facilities with such comments as "we are dedicated to reducing risk to patients; we err on the side of caution and work diligently to ensure our patients get the highest standard of care." "Measures to insure patient safety are in place throughout the institution ie. pharmacy with drug interactions, baby safe L & D, checks and double checks for paps and lab results…The measures are routinely reevaluated and changed if needed." "As a surgeon, our weekly morbidity and

mortality conferences continually remind us of our human ability to err. It is an excellent opportunity to re-hash the events, often related to patient safety – and to assess how things could have been done differently and what other physicians may have done in the same situation." "I perceive the climate at this institution to be one of careful monitoring of clinical errors and one where every attempt is made to improve the safety in the environment." "We work together to improve any issues and to make all patients safe here."

Perceptions About Leadership Concern for Patient Safety

Perception about leadership concern for patient safety was the third conceptual component assessed by the Patient Safety Climate Survey. Questions 9, 10, 15, and 19 address this construct. Although respondents view leadership positively on the Likert scale items, 113 respondents specifically addressed leadership as a patient safety issue. These responses were coded as a sub-set of culture (cul-lead). Three themes dominated these responses: there is a lack of central focus, communication, and teamwork regarding patient safety; senior leaders are more concerned with looking good or meeting their own career goals than with the needs of the organization, and leaders do not provide adequate resources to ensure a safe environment for patients. "Senior officers are not willing to communicate with their staff NCOs to make improvements for staff and patients and are more concerned with relying on their own perceptions of what needs to be changed so they will have a great OER." "I think the command is more worried about the numbers of people being treated than how the patient is cared for." "The lack of the leadership to find out the problems and not discuss the solutions with the persons doing the work, elitism." I believe that the higher in the command structure the more a person is concerned with career/unit reputation. The closer to the worker bee level, the greater the genuine emphasis on patient safety." "Doing more with less inhibits complete patient safety.

If patient safety was a true concern for those in high leadership positions, then the dilemmas faced by clinicians and ancillary support staff would be heard." "I am not sure that the leaders have looked closely at the safety issues re increased workload in many areas without increasing staff to care for them."

A recurrent theme throughout the responses from all MTFs was the frustration at the lack of sufficient resources to accomplish the AMEDD mission. Staffing shortages attributed to the drawdown, to frequent deployment of essential personnel, to multiple taskings not related to patient care, and to leadership not acknowledging when critical levels are reached, are cited by 864 respondents as a patient safety issue in their facility. Of those 864 respondents, 805 labeled staffing the number one patient safety issue where they work. The 805 responses include 475 from eight MEDCENs (59 %), 310 from 20 MEDDACs (39 %), and 18 from 6 free-standing Health Clinics (2 %). "Tired, overworked, and underpaid personnel may try to cut corners, and may lack the time to pay sufficient attention to detail. Thus, the climate is right for mistakes to happen." "The number one issue is the shortage of appropriate (numbers and skill levels) nursing and ancillary staff to consistently provide safe care." "Trying to take care of too many patients with too few resources, ie. not enough space, not enough staff, not enough money." "Too many patients for the number of doctors." "Poor staffing resulting in inadequate care." "Understaffing to the point of unsafe care of our patients." A MEDDAC respondent provided this assessment: "Staffing and budget. We are having to do too much with too little. I used to be proud of Army medicine. I am still proud of the people, but NOT the system. It is not the fault of the leadership here. The entire system is withering on the vine. I see military medicine being phased out of existence except for a small deployable base."

Respondents voiced concern about the inexperience and lack of training of direct care providers. Often cited were the lack of experienced nursing staff on the floors; young and inexperienced clinicians in a remote environment; minimally trained, inexperienced medics and Physician Assistants, and interns and residents in the Army Medical Centers. "There is not enough civilian and military leadership to foster and develop such diverse group of new professionals." "Requiring nurses to work outside their area of training" is identified as a potential reason for medical errors. "Nurses in our facility are asked to care for infants, children, pregnant women, active duty, and retirees in settings including ER, Ward, Clinic, ICU, OR".

"The smaller MEDDACs have too great of a diverse population on a single floor (peds and med/surg and ortho and gyn patients)" "Cross trained nurses asked to 'know a little about a lot' of problems rather than the expert, highly trained specialists that assure good patient care." The problem of inexperienced staff is compounded by the lack of appropriate oversight. "Unsupervised resident trainees and medical technicians who perform their process and procedures without direct supervision and correction from senior leaders and supervisors," are identified as a patient safety issue at several of the MEDCENs. Additional observations include: "Young nursing staff start out well-meaning and eager. But they appear to be far removed from direct supervision." "There are too many essentially unsupervised PAs and inexperienced GMOs." The perception is that the leadership is aware of the problem, but has not or can not take action to resolve the issue. "Senior MEDCOM leadership is in practice only pushing patient numbers, and not backing providers up in the need for patient care (on paper, and in surveys such as this, they advocate patient safety, but in reality ignore the largest contributor to physician/ nurse/ medic errors: insufficient staffing and emphasis on patient numbers)."

Patient Safety Issue Themes from Responses to Question 20

Culture of Blame/ Negative Leadership/ Not Reporting Errors/ Accountability

As previously discussed, a culture of blame exists within the AMEDD. This has led to an under-reporting of medical errors and close calls, so we do not know the extent of the threat to our patients' safety. In addition to those comments specifically addressing blame, respondents illustrate the blaming culture by emphasizing the need for accountability and attention to detail by their coworkers. Comments include: "lack of adequate attention to detail and thoroughness by staff (providers, pharmacists, nurses, etc.) in what they do, particularly related to practice/ procedure variances." "Carelessness of staff in giving medications/ treatments; lack of attention to detail, and just plain laziness!"

Inadequate Staffing/ Lack of Time/ Inexperience-Lack of Training/ Continuity of Care

These human resource issues speak to the frustration with the current "do more with less" philosophy prevalent in the AMEDD. In addition to the comments about inadequate staffing and lack of experienced personnel previously quoted, the following bullets illustrate the stress, disruption in continuity of care, and missed diagnoses attributed to the perceived emphasis on quantity rather than quality of care. "Patient safety and clinical errors related to lack of continuity of support/ nursing personnel. Continual retraining and lack of job knowledge and institutional memory directly and adversely affect both productivity and more importantly, patient care." "Poor continuity of care due to seeing multiple providers and not having records for appointments." "Patients receiving episodic care, thru the ER, without adequate Primary care FU for complex medical issues." "Fragmented patient care leading to misdiagnosis or incomplete follow-up of abnormal findings." "My number one Patient Safety issue is the ability for clinicians to follow-up on lab and test results; we are so far extended because the 'senior

members' or commanders are so worried about our 'numbers' that we are overextended which impairs our ability to give adequate follow-up to patients." "Access to TIMELY patient care." "Providers are rushed by 15 minute ("put out the fire") visits (some patients require longer visits or the system should allow at least 20-30 minutes for initial visits so that a good baseline history and plan for continued care can be completed)." "Residents work long hours and are seeing pts, making clinical decisions and doing procedures when very, very tired." "Personnel are stressed because there is not enough help to allow adequate time to prevent errors." The patient safety issues in this facility relate directly to the unmitigated stress placed on individuals. Trying to meet the demands of the chain of command in addition to being tasked from others i.e. GPRMC, MEDCOM, and OTSG. When one finishes being jerked around, concentrating on the normal business at hand, often the focus is distorted."

Facilities/ Parking/ Housekeeping/ Falls/ Equipment/ Infection Control/ Needle Sticks

The environment of care also creates a challenge to ensuring patient safety in our MTFs. "The lack of appropriate instruments and supplies is as much a problem as errors in treatment." "There is never enough money to buy modern equipment so that we can take better care of our patients." "Lack of accessible and safe wheelchairs on wards and at facility entrances." Wheelchairs were mentioned by 32 of the 164 respondents who named equipment as the primary patient safety issue." "Facility is old, repairs are bandaid fixes that don't solve the problems. Constant construction to update facility sets up an atmosphere for unsafe practices." "Space." "Aging infrastructure." "Physical access for disability patients." "Fire evacuation." "Broken elevator." "Unshoveled snow/ ice." "Slippery floors." "Patient safety in the parking lot." "Slips, trips, and falls." "Spills in the main corridors." "Working with patients/ blood without gloves."

"Employee hand washing/ sterile procedures." "Handling of hazardous materials."

Medication Errors

Medication errors, whether related to prescribing and ordering (47) by the provider, dispensing (68) by the pharmacist, or administering (150) by the nurse or patient him/ herself, were cited as the number one patient safety issue by 920 respondents, or 15.2 % of those who answered Question 20. Of these, 431 simply identified "medication errors" with no further narrative. Other respondents attributed medication errors to "the system is antiquated and needs additional checks that allow the use of computerized checks and patient identification to reduce the risk of errors." "Medication and treatment errors (both omission and commission) by nursing staff and medical staff R/T personnel turnover, perpetual new staff, and teaching environment." "Poor handwriting that results in drug dosage or drug type errors." "Med errors due to incorrect transcription of orders." "Medication errors related to distractions." "Medication errors, I feel that even though there are numerous checks, these still occur frequently." "Medication errors, particularly as CIS orders are automatically renewed, copied, or pasted." "From my perspective the number one safety issue is Medication Errors. Education and disciplinary action for over 50 years have not been useful enough to combat this problem. If technologies are available to help decrease these errors then they should be purchased…" "Medication errors and missed schedules due to understaffing in pharmacy and nursing." "Med errors = too many distractions during dispensing process: telephone, info about TRICARE, peak hours, etc." "Drug interactions." "Wrong medication either through incorrect prescription or through inappropriate filling at pharmacy."

In addition to the four major themes enumerated, 146 respondents identified children accompanying parents or siblings on appointments and being left unattended during the visit as a

source of injury to the child or to other patients in the clinic. "The safety issue that concerns me most is having extra children in the clinics. These extra children distract the parents and providers and are often engaged in disruptive and dangerous activities while the other child is being seen." Security of the facility and safety of the staff are additional safety issues identified by 105 respondents. "Lack of security in the ED and hospital." "Too many unauthorized personnel in hospital." Lack of security after clinic hours, doors remain open without security staff." "Violent patient or relative." "No way of knowing if contraband items are brought into the hospital." Table 3 and the revised code book (Appendix G) describe additional safety issues identified by respondents.

Responses to Question 20 are consistent with the literature regarding the current state of patient safety efforts in health care. At a national patient safety conference in Dallas, Texas held in October 2001, ninety-two percent (92 %) of attendees who responded to a poll believe that more can be done to adequately address and reduce medical errors. Only 16 % said that the healthcare community is effectively using technology to aid patient safety initiatives. Respondents to the poll cited reasons why medical errors continue: 1) outdated or overly complex processes, policies, and procedures, 2) lack of oral or written communication, and miscommunication, 3) lack of resources, and 4) excessive workloads resulting in distraction or inattention to detail. Challenges to reducing medical errors cited by the respondents include: commitment from personnel at all levels within a health care organization, inadequate error reporting due to fear of punitive actions, and the need for a patient safety champion within each organization (Quality Update, 2001).

Conclusion and Recommendations

The purpose of this study was to analyze responses to the MEDCOM Patient Safety Climate Survey to: 1) assess the corporate culture and climate, 2) identify respondents' perceptions of barriers to reporting medical errors, 3) prioritize patient safety issues identified by the respondents, and 4) make recommendations for improving patient safety throughout the AMEDD. Analysis of the Patient Safety Climate Survey revealed that the culture in MTFs throughout the AMEDD is one of blaming the individual rather than fixing the system when medical errors occur. This is consistent with the literature, which reports that health care environments traditionally emphasize personal responsibility, autonomy, and accountability in response to medical errors. Early in the education process, these principles are internalized by physicians and nurses to such an extent that the dominant emotion felt by health care workers who make a mistake is not fear of punishment, but rather shame. This culture is reinforced by human nature, which seeks to blame someone for bad outcomes, and by the legal system, which looks for someone to pay (Wears & Leape, 1999). This punitive, or blaming, culture is identified as the fundamental barrier to improving patient safety in health care (Buerhaus, 2001).

A "New Look" Approach to Medical Errors

How does one change the culture of health care organizations? Extensive study of other high-risk industries such as the airline industry, nuclear power plants, and the space program, provide a fundamentally different approach to error than that traditionally applied by the health care industry. This "New Look" at medical errors is characterized by the following: 1) emphasis on systems rather than people, 2) non-punitive approach, 3) recognition of the multifactorial nature of error, 4) assumption that errors will occur, 5) emphasis on caregiver interactions, and 6) "blunt end, versus "sharp end" investigations of error (Wears & Leape, 2001). Utilizing the

results of the Patient Safety Climate Survey and the six components of the "New Look" model, the following are recommendations to MEDCOM for changing the culture of the AMEDD, facilitating reporting of errors, eliminating barriers to reporting, and improving patient safety in Medical Treatment Facilities.

Emphasis on Systems Rather than People

An *emphasis on systems rather than people* requires redesign of processes to reduce complexity. Analysis of accidents in the nuclear power and aviation industries have illustrated that the underlying complexity of operations contributes to human performance problems. Simplifying the operation of the system improves its reliability and allows humans in the system to operate more effectively (Woods, 2001). Health care delivery includes many complex processes, from the prescribing, dispensing, and administering of medications to identifying, verifying, and operating on the correct patient or surgical site. Redesign of such processes to include automation, such as bar codes for medication systems, and uniform implementation of policies for surgical site identification can decrease complexity and reduce medical error. Woods cautions, however, that improper computerization can exacerbate or create new forms of complexity that confound operations (Woods, 2001). Of the 136 respondents who identified documentation as the primary patient safety issue in their MTF, one-third cited the "disparate systems for accessing patient data." "With the multiple computer systems (CHCS, CIS, and others) and their inability to interconnect and share data, there are bound to be episodes of missed data and inconsistent data. Additionally, the combined paper/computer generated chart invites clinical error in missed data/notes."

Non-punitive Approach

The AMEDD must subscribe to *a non-punitive approach* to medical errors. Errors waiting to happen, adverse events, and near misses are opportunities to learn about and improve the system. Formal sanctions, such as loss of privileges, and informal ones, like remedial education or embarrassment, only serve to stifle reporting and hide errors so that no one can learn from them and they continue to recur (Wears & Leape, 1999). The stated goal of the AMEDD Patient Safety Program is to improve incident reporting through the adoption of a non-punitive reporting approach (USAMEDCOM, Patient safety climate survey, August 15, 2001). BG William Bester, Deputy Chief of Staff for Operations, Health Policy and Service, and the Chief of the Army Nurse Corps said that the success of the Patient Safety Program depends on the creation of a culture of safety in all MTFs. Incident reporting systems provide a viable and relatively inexpensive means to obtain data on medical errors and adverse events. No research studies have correlated the impact of incident reporting on patient safety outcomes, however, because incident reporting has been shown to be of value in other industries, health care organizations may be able to replicate their safety improvement successes if the data collected are used to improve organizational performance rather than to generate individual performance evaluations (Wald & Shojania, 2001).

To date, learning and improvement from health care accidents and incidents has been limited, partly because of the fear of blame and litigation. Emphasis must shift from looking at incidents one at a time to analyzing aggregate data and implementing sustained improvements. There must be feedback to and from health care providers about how what was learned is relevant to their practice. To enhance learning, regional centers such as the Veterans Health Administration Centers for Inquiry allow collaboration among multiple health care systems and

sharing of lessons learned (Woods, 2001). Establishment of the USAMEDCOM Patient Safety Center facilitates this collaboration among MTFs. In order for MTFs to comply with the directive of the Defense Authorization Act for Fiscal Year 2001 to collect, assess, and report on the nature and frequency of errors related to patient care, an up-to-date, corporate-wide information management system is essential. Currently, many MTFs still report incidents by stubby pencil on DA Form 4106 (Appendix H), or the new MEDCOM Test Form 731-R (Appendix I), and the numbers are tracked by an individual in the risk management office. Those facilities using the automated DA 4106 on CHCS to report incidents still lack comprehensive aggregation and tracking ability.

A visit to Baptist Health System in San Antonio to view the "Occurrence Reporting Web" they have developed for their five hospitals and corporate office illustrated the importance of a user-friendly system for use across the AMEDD. Baptist Health System personnel can report medical errors and employee injuries to one central data base on their intranet. A variety of web pages allow the reporting of medication errors, falls, adverse drug reactions, and other incidents with a series of pull down menus designed to document all information relevant to the event. Their acting Risk Manager reported that since "going live" in November 2001, the number of error reports system-wide has increased from 200 to 900 per month. In spite of the increased number of incidents reported, the workload is comparable to what it was when the Risk Manager was manually entering the 200 incidents per month. Aggregation and analysis of data used to make recommendations to improve patient safety has been greatly simplified at Baptist Health Systems by this reporting tool.

I recommend that MEDCOM make the development or purchase of a corporate-wide error reporting system an immediate priority. Dr. James Bagian, director of the Veterans Health

Administration (VHA) National Center for Patient Safety, cites adverse event and close call reporting, analysis, and action as the VHA's greatest achievement in the area of patient safety. In 1997, the VHA had a close call reporting rate of 0.1%. In 2002, it is about 90%. Because close calls occur more frequently than the actual event they portend, the risk can be identified and mitigated before an adverse event occurs. Group analysis of an adverse event or close call followed by development of an appropriate corrective action plan illustrates to staff that something good will result from reporting a problem. The actions that follow reporting are crucial to the success of an error reporting system (Mears & White, 2002). Another testimonial for the importance of a user-friendly system of reporting errors is documented in *The Quality Letter*. Prior to implementation of an online management program, the 104-bed Baylor Medical Center at Grapevine (BMCG) in Texas, relied on paper reporting of adverse events. The system was cumbersome and ineffective and resulted in under-reporting of adverse events. With the online program, reporting of adverse events and close calls jumped 250 to 500 percent (from 20 to 30 reports per month) and has continued at a rate of 90 to 150 reports a month. The time for follow-up resolution of events decreased 25 to 50 %, from two or three weeks to within an hour or two (Atherton, 2001).

Emphasis on the Multifactorial Nature of Error

The *multifactorial nature of error* must be addressed to improve the patient safety climate. Traditionally, providers were expected to be infallible. We must recognize that no one can be perfect and we work in imperfect systems. Simplifying and standardizing procedures, improving communication among providers and patients, using computerized documentation systems to avoid misinterpreting orders, providing adequate staffing so that workers are well rested and have time to pay attention to details will address factors that contribute to medical

error. Just as commercial airliners are equipped with more than one engine so that the "fault" of an engine failure can occur without resulting in disaster, health care systems must be designed with back-ups in case of a "fault" in the process (Mears & White, 2002).

Assumption that Errors Will Occur

In the "New Look" model is an *assumption that errors will occur.* The AMEDD must drop the "zero-defects" mentality still pervasive in the military. Instead of emphasizing the role of personal accountability in preventing errors, and holding providers to an unattainable standard of perfection, it must be acknowledged that lapses, slips, and mistakes will inevitably occur. Emphasis must be directed toward redesigning work systems to reduce the ability to make errors, identifying errors to caregivers before they affect the patient, and providing safeguards to minimize the effect of errors on patients. The removal of concentrated potassium chloride from patient units and "fail safe" infusion pumps illustrate the concept of system redesign (Wears & Leape, 1999).

Emphasis on Caregiver Interactions

Emphasis on caregiver interactions emphasizes an interdisciplinary approach to providing health care. Because traditional health care contains hierarchical and territorial impediments, communication among health care providers is not optimal. Health care is not delivered by individuals in isolation, but requires a team effort that includes the patient, physician, nurse, other health care professionals, and ancillary personnel. Good communication among the members of the health care team has great potential to prevent medical errors (Wears & Leape, 1999).

Sharp End, Blunt End

Blunt end versus sharp end investigations of error change the focus of error investigation from the "sharp end," where patients and caregivers interact, to the "blunt end" where organizational policies, procedures and resource allocation decisions are made. The many factors that contribute to medical errors are concentrated at the blunt end of the spectrum. A systemic approach to error reduction has been successful in other high-risk industries and can be applied to the medical environment to improve patient safety (Wears, & Leape, 1999).

Conclusion

As a result of these initiatives, the AMEDD should become a safer health care environment, not only for patients, but also for visitors and staff. Current rates of reporting of medical errors and near misses should increase as personnel become convinced that the organization's leaders are committed to gathering data for the purpose of restructuring processes, not to blame individual care givers for mistakes. A change in emphasis from reactively analyzing medical errors to proactively assessing processes for their risk of causing patients harm would be indicative of a climate change. The ability of all AMEDD personnel to articulate their responsibility to be actively involved in patient safety and risk reduction would provide a measure of the success of staff education and involvement in improving patient safety. It is expected that all personnel will appropriately report any adverse or near-miss events.

A resurvey of the AMEDD after January 2003 should provide responses indicative of a corporate climate that is evolving to one in which personnel feel safe to report errors, engage in problem solving processes, and perceive the leaders to be committed to patient safety. Implementation of the AMEDD Patient Safety Program will ensure compliance with Joint

Commission new patient safety standards and contribute to a successful JCAHO survey for each MTF.

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Appendix A

THE DEFENSE AUTHORIZATON ACT

TITLE VII-HEALTH CARE PROVISIONS

Subtitle E-Joint Initiatives With Department of Veterans Affairs

SEC. 754. PATIENT CARE REPORTING AND MANAGEMENT SYSTEM.

(a). Establishment.--The Secretary of Defense shall establish a patient care error reporting and management system.

(b). Purposes of System.--The purposes of the system are as follows:

(1) To study the occurrences of errors in the patient care provided under chapter 55 of title 10, United States Code.

(2) To identify the systemic factors that are associated with such occurrences.

(3) To provide for action to be taken to correct the identified systemic factors.

(c). Requirements for System.--The patient care error reporting and management system shall include the following:

(1) A hospital-level patient safety center, within the quality assurance department of each health care organization of the Department of Defense, to collect, assess, and report on the nature and frequency of errors related to patient care.

(2) For each health care organization of the Department of Defense and for the entire Defense health program, patient safety standards that are necessary for the development of a full understanding of patient safety issues in each such organization and the entire program, including the nature and types of errors and the systemic causes of the errors.

(3) Establishment of a Department of Defense Patient Safety Center within the Armed Forces Institute of Pathology, which shall have the following missions:

(A) To analyze information on patient care errors that is submitted to the Center by each military health care organization.

(B) To develop action plans for addressing patterns of patient care errors.

(C) To execute those action plans to mitigate and control errors in patient care with a goal of ensuring that the health care organizations of the Department of Defense provide highly reliable patient care with virtually no error.

(D) To provide, through the Assistant Secretary of Defense for Health Affairs, to the Agency for Healthcare Research and Quality of the Department of Health and Human Services any reports that the Assistant Secretary determines appropriate.

(E) To review and integrate processes for reducing errors associated with patient care and for enhancing patient safety.

(F) To contract with a qualified and objective external organization to manage the national patient safety database of the Department of Defense.

(d) MedTeams Program.--The Secretary shall expand the health care team coordination program to integrate that program into all Department of Defense health care operations. In carrying out this subsection, the Secretary shall take the following actions:

(1) Establish not less than two Centers of Excellence for the development, validation, proliferation, and sustainment of the health care team coordination program, one of which shall support all fixed military health care organizations, the other of which shall support all combat casualty care organizations.

(2) Deploy the program to all fixed and combat casualty care organizations of each of the Armed Forces, at the rate of not less than 10 organizations in each fiscal year.

(3) Expand the scope of the health care team coordination program from a focus on emergency department care to a coverage that includes care in all major medical specialties, at the rate of not less than one specialty in each fiscal year.

(4) Continue research and development investments to improve communication, coordination, and team work in the provision of health care.

(e) Consultation.--The Secretary shall consult with the other administering Secretaries (as defined in section 1072(3) of title 10, United States Code) in carrying out this section.

SEC. 742. PROCESSES FOR PATIENT SAFETY IN MILITARY AND VETERANS HEALTH CARE SYSTEMS.

(a) Error Tracking Process.--The Secretary of Defense shall implement a centralized process for reporting, compilation, and analysis of errors in the provision of health care under the defense health program that endanger patients beyond the normal risks associated with the care and treatment of such patients. To the extent practicable, that process shall emulate the system established by the Secretary of Veterans Affairs for reporting, compilation, and analysis of errors in the provision of health care under the Department of Veterans Affairs health care system that endanger patients beyond such risks.

(b) Sharing of Information.--The Secretary of Defense and the Secretary of Veterans Affairs--

(1) shall share information regarding the designs of systems or protocols established to reduce errors in the provision of health care described in subsection (a); and

(2) shall develop such protocols as the Secretaries consider necessary for the establishment and administration of effective processes for the reporting, compilation, and analysis of such errors.

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Appendix B

Department of Defense

INSTRUCTION

NUMBER 6025.17

August 16, 2001

ASD(HA)

SUBJECT: Military Health System (MHS) Patient Safety Program (PSP) (MHSPSP)

References: (a) Sections 742 and 754 of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001
(b) DoD Directive 6025.13, "Clinical Quality Management Program (CQMP) in the Military Health Services System (MHSS)," July 20, 1995
(c) DoD Directive 5154.24, "Armed Forces Institute of Pathology," October 28, 1996
(d) Section 1102 of title 10, United States Code
(e) through (g), see enclosure 1

1. PURPOSE

This Instruction:

1.1. Implements policy, assigns responsibility, and prescribes procedures under the authority of references (a) and (b), establishes a MHSPSP to identify and report centrally actual and potential problems in medical systems and processes and to implement effective actions to improve patient safety and healthcare quality throughout the MHS. The MHSPSP, to the extent practicable shall emulate the system established for reporting, compilation, and analysis of errors in the provision of healthcare under the Department of Veterans Affairs (DVA) healthcare system.

1.2. Prescribes procedures in every military medical treatment facility (MTF) for a dedicated program for avoiding medical errors and improving patient safety that is focused on prevention, not punishment, and on improving medical systems and processes to overcome preventable errors.

1.3. Establishes a MHS Patient Safety Center (MHSPSC), including a MHS Patient Safety Registry (MHSPSR) through the Armed Forces Institute of Pathology (AFIP) (reference (c)).

1.4. Establishes two Centers of Excellence (COE) in the MHSPSC to develop programs to improve communication, coordination, and teamwork in the provision of healthcare in MTFs and operational units.

1.5. Complies with the requirements for confidentiality of medical quality assurance (QA) records under 10 U.S.C. 1102 and DoD Directive 6040.37 (references (d) and (e)).

1.6. Establishes a Healthcare Team Coordination Program.

2. APPLICABILITY

This Instruction applies to the Office of the Secretary of Defense, the Military Departments, the Chairman of the Joint Chiefs of Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities of the Department of Defense (hereafter referred to collectively as "the DoD Components").

3. DEFINITIONS

Terms used in this Instruction are in enclosure 2.

4. RESPONSIBILITIES

4.1. The Assistant Secretary of Defense for Health Affairs under the Under Secretary of Defense for Personnel and Readiness shall:

4.1.1. Monitor the effectiveness of the MHSPSP and issue such additional guidance as needed.

4.1.2. Have the authority to grant exceptions to the requirements of this Instruction when indicated by unforeseen circumstances.

4.1.3. Establish appropriate cooperative arrangements between the MHSPSP and the Department of Veterans Affairs and other patient safety initiatives of the

Federal Government, State governments, and appropriate non-government organizations that are likely to promote the mutual success of such activities. Any such cooperative arrangements shall maintain the confidentiality of records and information under 10 U.S.C. 1102 and DoD Directive 6040.37 (references (d) and (e)).

4.1.4. Establish a Patient Safety Council that includes representatives of the Military Departments, TRICARE Management Activity (TMA), the AFIP, the DoD Office of General Counsel, the Uniformed Services University of the Health Sciences (USUHS) and such other governmental entities as the Assistant Secretary of Defense for Health Affairs (ASD(HA)) determines applicable. The Council shall review the reports from MHSPSC, patient safety initiatives in the MHS, other Federal Agencies and the private sector, and other patient safety issues in the MHS and report to the ASD(HA) no less than once a year on medical safety improvements and recommended policy changes.

4.2. The Secretaries of the Military Departments shall:

4.2.1. Implement this Instruction.

4.2.2. Authorize the Surgeons General of the respective Military Departments to participate fully in the MHSPSP, including initiatives to promote the objectives of the program, monitor for inappropriate use of information generated, and provide recommendations to the ASD(HA) for program improvements.

4.2.3. To ensure adequate representation and participation of the Military Departments, assign appropriate military personnel staff to the MHSPSC.

4.3. The Director of the Armed Forces Institute of Pathology shall establish and maintain the MHSPSC, which shall:

4.3.1. Establish and maintain the MHSPSR consistent with this Instruction.

4.3.2. Make all de-identified information in the MHSPSR available to the ASD(HA), the Secretaries of the Military Departments, the Surgeons General, the Director of the TMA, the President of the USUHS, and the MTF Commanders.

4.3.3. Review reports of adverse events, close calls, and root-cause analyses (RCA); analyze the data; develop and execute action plans for addressing patterns of patient care errors; review and integrate processes for reducing errors and enhancing patient safety and create and distribute quarterly reports, in accordance with subparagraph 5.6.2. The execution of action plans shall be through the Patient Safety Council.

4.3.4. Coordinate with other Federal Agencies on PSP activities, including the Department of Health and Human Services (DHHS) and the Department of Transportation (DOT), on functions of the MHS effecting the non-DoD Uniformed Services, the VA, and the Agency for Healthcare Research and Quality of the DHHS.

4.3.5. Coordinate, promote, and perform research to support the MHSPSP and the Healthcare Team Coordination Programs (HCTCP) using information maintained by the MHSPSR.

4.3.6. Have authority to contract with a qualified and objective external organization to manage the national patient safety database of the Department of Defense.

4.3.7. Monitor patient safety activities of State governments, and non-governmental organizations and include in quarterly reports under subparagraph 5.6.2. information derived from such sources that shall support and promote patient safety activities of the MHS.

4.3.8. Establish two COEs for the development, validation, proliferation, and sustainment of the HCTCP, one of which shall support all fixed military healthcare organizations, the other of which shall support all combat casualty care organizations.

4.3.9. Provide, through the ASD(HA), to the Agency for Healthcare Research and Quality of the DHHS any reports that the ASD(HA) determines applicable.

4.3.10. Provide other support for an effective MHSPSP, including such other actions, as the ASD(HA) may direct.

4.4. The Director, TMA shall support the successful implementation of the MHSPSP.

4.5 The President, Uniformed Services University of the Health Sciences shall, in the operation of education, training, clinical, and research programs of USUHS, promote the objectives of the PSP.

5. PROCEDURES

5.1. Establishment of a MTFPSP. The Commander of every MTF shall establish and implement a PSP consistent with this Instruction and applicable Service regulations. The administration of the MTFPSP shall be through a MTF Patient Safety

Office or Directorate (MTFPSO/D), which shall function as an integral part of the QA process of the MTF.

5.1.1. The MTFPSP shall have procedures and standards for the following activities:

5.1.1.1. Receipt from clinical and administrative staff and patients or their families of reports of adverse events, sentinel events, and close calls.

5.1.1.2. Analysis or review of reports of adverse events, sentinel events, and close calls, including written findings and recommendations on potential improvements in systems and processes to reduce the frequency and severity of medical errors.

5.1.1.3. Prompt acknowledgement of reports and timely feedback to staff making reports of actions planned to improve patient safety.

5.1.1.4. Initiation of actions, through administrative and clinical staff and senior management, intended to improve patient safety with subsequent follow-up evaluation of their effectiveness.

5.1.1.5. Compiling, maintaining, and using data to identify additional opportunities to improve patient safety.

5.1.1.6. Submission of information and reports from the MTF to the MHSPSR in the MHSPSC at the AFIP.

5.1.1.7. Provide guidance to staff to ensure that in cases in which serious medical errors cause harm to a patient, a qualified healthcare provider shall inform the patient or applicable family members. Information provided may not include medical QA records and information prohibited from disclosure by 10 U.S.C. 1102 (reference (d)). That information is provided as a matter of clinical policy and does not affect any rights or obligations in legal or administrative proceedings.

5.1.2 The MTF commander shall designate an individual as the Patient Safety Manager (PSM) to direct the MTFPSP and shall ensure that program activities receive interdisciplinary support from the MTF staff and other support necessary for an effective program. The PSM and other personnel designated by the MTF commander shall receive PSP training from the MHSPSC before the initiation of the program in the MTF.

5.1.3. All clinical and administrative personnel shall be educated about the MHSPSP and the MTF-related activities, encouraged to report adverse events, sentinel events, and close calls, to support program activities, and be given periodic updates on its procedures and activities.

5.1.4. Medical teams programs emphasizing communication, coordination, and teamwork techniques shall be included in the overall education program.

5.2. Joint Commission of Accreditation of Healthcare Organizations (JCAHO) Sentinel Event Standards

5.2.1 All sentinel events defined by JCAHO, as reportable to JCAHO, shall be reported. The completed RCA and action plan, consistent with JCAHO policy and time limits, shall be made available to JCAHO.

5.2.2. MTFs shall comply with JCAHO Patient Safety and Medical/Healthcare Error Reduction Standards.

5.3. Conducting RCA. The PSP shall include a RCA and action plan (or aggregate review under subparagraph 5.3.3., below) of adverse events and close calls scored as a "category 3" under the "Safety Assessment Code (SAC) Matrix" at enclosure 3. The MTFs are encouraged to conduct RCAs on other adverse events and close calls that they deem necessary.

5.3.1. The RCA (or aggregate review) and action plan shall include written findings regarding the underlying systems and processes involved in the event, including the identification of actual and potential problems in those systems and processes, and recommendations for corrective action plans. The RCA and action plan shall be completed and approved by the MTF commander within 45 days of the date on which the PSPM becomes aware of the adverse event.

5.3.2. The RCA and action plan shall be provided to the MTF official(s) with responsibility for the systems or processes involved so they may implement and evaluate the effectiveness of corrective actions.

5.3.3. A quarterly aggregate review may be performed instead of an individual event RCA for certain types of more common adverse events or close calls. The types of adverse events or close calls for which a quarterly aggregate review may be used are listed in enclosure 2. That list may be changed by an ASD(HA) memorandum. An aggregate review may not be used for any JCAHO reviewable sentinel events; an individual RCA shall be performed for all such events.

5.3.4. RCAs and aggregate reviews are conducted for improving medical systems and processes, not for personnel management. Although consideration of information discovered in the course of RCAs and aggregate reviews for personnel management matters is not prohibited, MTF commanders, credential, and/or privileging committees, medical malpractice claims peer review committees, and other entities charged with oversight of professional behavior and competence shall rely to the maximum extent practicable on information from other review systems and processes for those purposes. Limiting the use of PSP information to improve systems and processes is essential for promoting maximum staff support for and participation in the PSP.

5.4. Referral of Information on Intentional Unsafe Acts. The investigation of and consideration of corrective actions on intentional unsafe acts are not within the primary authority or responsibility of the PSP. If in the course of the activities of the PSP, information about intentional unsafe acts is revealed, the original report shall be referred to applicable command authorities. Primary authority to investigate and consider corrective actions on the matter shall be outside the PSP.

5.4.1. Findings of intentional unsafe acts that result from gross negligence or possible criminal activity shall be reported by the command authorities to the applicable military criminal investigative organization, and the Defense Criminal Investigative Service, OIG, DoD.

5.4.2. Some events fall within the definitions of both "adverse events" and "intentional unsafe acts." For example, an infant abduction shall be both a crime and a JCAHO-reportable sentinel event requiring a RCA. When an event appears to be both an "adverse event" and an "intentional unsafe act," primary authority and responsibility is outside the PSP. The PSP shall proceed with a review, including a RCA, if applicable, of the systems and processes of the facility implicated in the actual or potential intentional unsafe act, but shall defer to the separate investigation and consideration on any matter of culpability of any person involved in the act.

5.5. Reporting to the MHSPSC. The manager of the MTFPSO/D shall submit regular reports (at least on a quarterly basis) to the MHSPSC, in accordance with guidance in enclosures 3 and 4.

5.5.1. The report(s) shall include all adverse events and close calls for which a RCA (or aggregate review) is required by subparagraph 5.3., above; copies of all RCAs and aggregated reviews completed during the reporting period and associated action plans; the number of intentional unsafe acts identified by the MTFPSP; and a report on other actions taken by the MTF based on lessons learned under the MTFPSP.

5.5.2. The data elements at enclosure 4 shall be used. Those elements may be changed by the ASD(HA) by memorandum.

5.5.3. The reports and other information (including copies of RCAs, aggregate reviews, and action plans) submitted to the MHSPSC shall not include names or other identifying information on patients or healthcare providers in adverse events, sentinel events, and close calls. All information received by the PSC shall be de-identified before entry into the registry.

5.6. Administration of the MHSPSC

5.6.1. The information reported to the MHSPSC shall be used exclusively for improving healthcare systems and processes that impact on medical errors and patient safety. MHSPSC information shall not be used for any adverse administrative, privileging or other personnel actions.

5.6.2. Analysis of the de-identified information submitted to the MHSPSC shall be used to provide quarterly reports to the ASD(HA), the Secretaries of the Military Departments, the Surgeons General of the Military Departments, the Director of TMA, the President of the USUHS, and each MTF commander. In coordination with the Patient Safety Council, information reported to the MHSPSC shall be used to develop and execute action plans for addressing patterns of actual or potential patient care errors and to promulgate patient safety standards for the MHS.

5.7. Confidentiality of Records and Information of the PSP. All records and information of the PSP, including those at each MTF, at the MHSPSC, stored in the MHSPSR, and at all other levels of the MHS, are medical QA records and are confidential under 10 U.S.C. 1102 and DoD Directive 6040.37 (references (d) and (e)). Aggregate statistical information at the DoD-wide or Service-wide levels may be provided consistent with references (d) and (e). Except as specifically authorized by this Instruction (such as for JCAHO sentinel events reporting under paragraph 5.2., above), PSP records or information shall not be disclosed unless authorized by references (d) and (e), and also either required by other applicable authority (such as a legally valid subpoena or order) or authorized by the ASD(HA).

5.8. HCTCP. The PSP includes implementation of the HCTCP, a focused effort to improve systems and processes affecting the integration of multiple healthcare disciplines to produce effective communication, coordination, and teamwork in delivering quality healthcare. The HCTCP shall be implemented in phases in all fixed and combat casualty care organizations and in all medical specialty departments and areas, beginning with emergency medicine and obstetrics and/or gynecology. Phasing shall be coordinated through the Patient Safety Council to result in DoD-wide phasing at a rate of not less than ten organizations in each fiscal year (FY) and not less than one medical specialty department or area in each FY.

6. INFORMATION REQUIREMENTS

The Military Treatment Facility Patient Safety Program Reports required by this Instruction have been assigned Report Control Symbol DD-HA(M)2129, Military Health System Patient Safety Registry Close Calls and Adverse Events Reports in accordance with DoD 8910.1-M (reference (f)).

7. EFFECTIVE DATE

This Instruction shall take effect 120 days from the date of issuance.

J. Jarrett Clinton, MD, MPH
Acting Assistant Secretary of Defense
(Health Affairs)

Enclosures - 4

E1. References, continued
E2. Definitions
E3. Safety Assessment Code
E4. Data Elements for Reports of RCAs and Aggregate Reviews

E1. ENCLOSURE 1

REFERENCES, continued

(e) DoD Directive 6040.37, "Confidentiality of Medical Quality Assurance (QA) Records," July 9, 1996
(f) DoD 8910.1-M, "DoD procedures for Management of Information Requirements," June 30, 1998
(g) Title 29, Code of Federal Regulations, Part 1960.70, "Reporting of Serious Accidents," current edition
(h) The Safe Medical Devices Act of 1970, Pub. L. 101-629

E2. ENCLOSURE 2

DEFINTIONS

E2.1. DEFINED TERMS

E2.1.1. Adverse Events. Occurrences or conditions associated with care or services provided that cause unexpected harm to a patient during such care or services. These may be due to acts of commission or omission. Adverse events do not include intentional unsafe acts. "Categorization of adverse events" is defined in enclosure 3. The method for categorizing events may be changed by an ASD(HA) memorandum.

E2.1.2. Sentinel Events. As defined by JCAHO, sentinel events are unexpected occurrences involving death or serious physical or psychological injury or risk thereof.

E2.1.3. Close Calls. An event or situation that may have resulted in harm to a patient, but did not, either by chance or through timely intervention. Such events have also been referred to as "near miss" incidents.

E2.1.4. Intentional Unsafe Act. Any alleged or suspected act or omission of a provider, staff member, contractor, trainee, or volunteer pertaining to a patient that involves a criminal act; a purposefully unsafe act; patient abuse; or an event caused or affected by drug or alcohol abuse. Intentional unsafe acts are matters for law enforcement, disciplinary system, or administrative investigation.

E2.1.5. Root Cause Analysis (RCA). A process for identifying the basic or contributing causal factors associated with adverse events and close calls. A root cause analysis includes the following characteristics:

E2.1.5.1. The review is interdisciplinary in nature with involvement of those closest to the process.

E2.1.5.2. The analysis focuses primarily on systems and processes rather than individual performance.

E2.1.5.3. The analysis digs deeper by asking "what" and "why" until all aspects of the process are reviewed and all contributing factors are identified.

E2.1.5.4. The analysis identifies changes that may be made in systems and processes through either redesign or development of new processes or systems that may improve performance and may reduce the risk of adverse events or recurrence of close calls.

E2.1.6. Aggregate Review. The process of analyzing recurring incidents, events, or close calls (such as medication errors) for trends and patterns to use for process improvement.

E3. ENCLOSURE 3

SAFETY ASSESSMENT CODE MATRIX

E3.1. SEVERITY CATEGORIES

E3.1.1. Key factors for the severity categories are extent of injury, length of stay, and level of care required for remedy. The four categories, below, apply to actual adverse events (see Figure E3.F1., below).

E3.1.2. For actual close calls and/or adverse events, assign severity based on the patient's actual condition. Some incidents that occur may have such an overwhelming potential for a catastrophic event that an RCA also shall be necessary, but that determination shall be left to the discretion of the MTF.

Figure E3.F1. Four Categories of Adverse Events

Catastrophic Patients with Actual: Death or major permanent loss of function (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying condition (i.e., acts of commission or omission). Suicide (inpatient or outpatient). Rape. Hemolytic transfusion reaction. Surgery/Procedure on the wrong patient or wrong body part. Infant abduction or infant discharge to the wrong family. Death or major permanent loss of function that is a direct result of injuries sustained in a fall; or associated with an unauthorized departure from an around-the-clock treatment setting; or the result of an assault or other crime.	Major Patients with Actual: Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying conditions (i.e., acts of commission or omission). Disfigurement. Surgical intervention required. Increased length of stay or level of care of 3 days or more.
Moderate Patients with Actual: Increased length of stay or higher level of care for less than 3 days.	Minor Patients with Actual: No increased length of stay or increased level of care.

E3.2. PROBABILITY OF RECURRENCE

E3.2.1. Like the severity categories, the probability of recurrence applies to actual adverse events and close calls.

E3.2.2. In order to assign a probability rating for an adverse event or close call, it is ideal to know how often it occurs at your facility. Sometimes, the data shall be easily available because it is routinely tracked (e.g., falls with injury, medication errors; etc.). Sometimes, getting a feel for the probability of events that are not routinely tracked shall mean asking for a quick or informal opinion from staff most familiar with those events. Sometimes it shall have to be a personal best educated guess.

E3.2.2.1. High. Likely to occur immediately or within a short period of time

E3.2.2.2. Medium. Likely to occur several times in 1 to 2 years.

E3.2.2.3. Low. May happen greater than 2 years.

How the SAC Matrix Looks

Figure E3.F2. Matrix Sample

Severity and Probability	Catastrophic	Major	Moderate	Minor
High	3	3	2	1
Medium	3	2	1	1
Low	3	2	1	1

E3.4. HOW THE SAC MATRIX WORKS

When pairing a severity category with a probability category for either an actual event or close call, that shall result in a ranked matrix score (3 = highest risk, 2 = intermediate risk, 1 = lowest risk). These ranks, or SACs may then be used for doing comparative analysis, and, for deciding who needs to be notified about the event.

Footnotes

[1] All known reporters of events, regardless of SAC score (1, 2, or 3), shall receive applicable and timely feedback.

[2] The risk manager shall refer adverse events or close calls related solely to staff, visitors or equipment and/or facility damage to relevant facility experts or services on a timely basis, for assessment and resolution of those situations.

[3] A quarterly aggregate RCA may be used for two types of calls (that includes all events or close calls other than actual SAC 3s, since all actual SAC 3s require an individual RCA). Those two types are "falls" and "medication errors." The use of aggregate analysis serves two important purposes. First, greater utility of the analysis (i.e., trends or patterns not noticeable in individual case analysis are more likely to show up as the number of cases increases). Second, it makes wise use of the RCA team's time and expertise. Facilities are encouraged to perform an individual RCA rather than aggregate review on any adverse event or close call that they think merits that attention, regardless of the SAC score.

[4] 29 CFR 1960.70 (reference (g)) requires each Federal Agency to notify OSHA within 8 hours of a work-related incident, which results in the death of an employee or the in-patient hospitalization of 3 or more employees.

[5] The "Safe Medical Devices Act of 1990" (reference (h)) requires reporting of all incidents in which a medical device may have caused or contributed to the death, serious injury, or serious illness of a patient or another individual.

E4. ENCLOSURE 4

DATA ELEMENTS FOR REPORTS OF RCAs AND AGGREGATE REVIEWS

E4.1. ROOT CAUSE ANALYSIS

E4.1.1. Medication errors.

E4.1.2. Attempted and/or actual patient suicides.

E4.1.3. Wrong site surgery.

E4.1.4. Patient injury in restraints.

E4.1.5. Transfusion error.

E4.1.6. Patient elopement.

E4.1.7. Infant abduction and/or wrong family.

E4.1.8. Fire.

E4.1.9. Equipment and/or utility system failure.

E4.1.10. Delay in treatment.

E4.1.11. Patient falls.

E4.1.12. Procedure errors and/or problems.

E4.1.13. Informed consent.

E4.1.14. Instrument and/or sponge count.

E4.1.15. Lab procedures.

E4.1.15. Age.

E4.1.16. Sex.

E4.1.17. Date and time of the event.

E4.1.18. Type of event (medication error, wrong site surgery, and patient suicide; etc.).

E4.1.19. Inpatient or outpatient.

E4.1.20. Type of unit (if inpatient).

E4.1.21. Summary of event.

E4.1.22. Specific factors contributing to the event (will vary with type of event).

E4.1.23. Work hours of involved staff if applicable (categorize as "lesser than 10 hours," "greater than 10 - 24 hours," or "greater than 24 hours").

E4.1.24. Information sources (do not include names).

E4.1.25. Patient outcome.

E4.1.26. Specific findings (brief statement of the identified root cause).

E4.1.27. Associated JCAHO standard.

E4.1.28. Specific actions recommended.

E4.1.29. Type of actions (educational, process redesign, and environmental redesign; etc.).

E4.2. DATA ELEMENTS FOR AGGREGATE REVIEWS

E4.2.1. Falls.

E4.2.1.1. Age.

E4.2.1.2. Sex.

E4.2.1.3. Date and time of the event.

E4.2.1.4. Prior fall(s).

E4.2.1.5. Designated as high risk for falls?

E4.2.1.6. Need for assistance with mobility, transfers and/or ADLs.

E4.2.1.7. Gait or balance limitations.

E4.2.1.8. Incontinence.

E4.2.1.9. Confusion or memory problems.

E4.2.1.10. Other limitations.

E4.2.1.11. Related medical conditions.

E4.2.1.12. Medication effects.

E4.2.1.13. Assistive devices.

E4.2.1.14. Communications issues.

E4.2.1.15. Environmental problems.

E4.2.1.16. Summary of what occurred and treatment plan changes.

E4.2.1.17. Comments.

E4.2.2. Medication Errors

E4.2.2.1.1. Age.

E4.2.2.1.2. Sex.

E4.2.2.1.3. Date and time of the event.

E4.2.2.1.4. Inpatient or outpatient.

E4.2.2.1.5. Type of unit (if inpatient).

E4.2.2.1.6. Processes related to the event (ordering, transcribing, dispensing, administering, and documenting).

E4.2.2.1.7. Work hours of involved staff if applicable (categorize as "less than 10 hours," "greater than 10 - 24 hours," "greater than 24 hours").

E4.2.2.1.8. What happened ("yes" or "no" to following):

E4.2.2.1.8.1. Medication given despite known allergy.

E4.2.2.1.8.2. Omission.

E4.2.2.1.8.3. Overdose.

E4.2.2.1.8.4. Incorrect patient identification.

E4.2.2.1.8.5. Incorrect medication identification.

E4.2.2.1.8.6. Incorrect dose.

E4.2.2.1.8.7. Incorrect route.

E4.2.2.1.8.8. Incorrect schedule.

E4.2.2.1.8.9. Equipment failure.

Appendix C

MEDCOM Reg 40-41

DEPARTMENT OF THE ARMY
HEADQUARTERS, UNITED STATES ARMY MEDICAL COMMAND
2050 Worth Road
Fort Sam Houston, Texas 78234-6000

MEDCOM Regulation
No. 40-41

14 January 2002

Medical Services
THE PATIENT SAFETY PROGRAM

Supplementation of this regulation and establishment of forms other than MEDCOM forms are prohibited without prior approval from HQ MEDCOM, ATTN: MCHO-Q.

1. HISTORY. This is the first printing of this publication.

2. PURPOSE. This publication–

a. Establishes an Army Medical Department (AMEDD) Patient Safety Program (PSP) to identify and centrally report actual and potential problems in medical systems and processes and to improve patient safety (PS) and health care quality throughout the AMEDD.

b. Establishes a Patient Safety Center (PSC) at the U.S. Army Medical Command (USAMEDCOM) to facilitate identification, management, communication, coordination, and teamwork in corporate PS systems and process improvement initiatives.

c. Establishes procedures for every military treatment facility (MTF) to execute a dedicated program for avoiding patient harm and improving PS.

d. Defines processes, within the MTF performance improvement structure, for assessing high-risk functions/processes; reporting, reviewing and analyzing risk and safety data; and initiating corrective measures to reduce and prevent future occurrences.

e. Supports the use of a standardized PS event reporting process; corporate database; and methodology for collecting, aggregating, and analyzing both individual MTF as well as corporate PS data.

f. Establishes a standardized method for categorizing PS events based on event severity and probability of recurrence.

g. Establishes a standardized methodology for conducting aggregate and root cause analyses (RCA) and documentation of action plans for improvement.

h. Clarifies the types of PS events and/or professional behaviors requiring evaluation and management through established individual peer/performance review processes.

i. Provides guidance for implementation of Department of Defense (DOD) Instruction (DODI) 6025.17 and the requirements for confidentiality of medical quality assurance (QA) records under Title 10, United States Code (USC), Section 1102 (10 USC 1102) and DOD Directive 6040.37.

3. REFERENCES. Required and related publications are listed in appendix A.

4. EXPLANATION OF ABBREVIATIONS AND TERMS. Abbreviations and special terms are explained in the glossary.

5. APPLICABILITY. This regulation applies to personnel in all USAMEDCOM installations and activities.

6. RESPONSIBILITIES.

a. The Commander, USAMEDCOM/The Surgeon General (TSG), as the senior medical officer in the Department of Army, will--

(1) Establish policy and standardized procedures to implement DODI 6025.17 and facilitate the safe delivery and quality of health care provided to all categories of beneficiaries.

(2) Promote a blameless culture through active support of the AMEDD PSP and communication of PS principles throughout all levels of the organization.

(3) Allocate resources required to initiate and sustain a comprehensive AMEDD PSP.

(4) Support establishment of a standardized AMEDD PS database and MTF reporting requirements for effective program monitoring and evaluation.

(5) Delegate to MTF commanders the responsibility and accountability for implementation and sustainment of the PSP within their MTFs.

b. In accordance with DODI 6025.17, the Military Health System Patient Safety Center at Armed Forces Institute of Pathology (AFIP) will--

(1) Identify effective strategies/actions to improve PS and health care quality throughout the military healthcare system (MHS).

(2) Prepare and distribute MHS quarterly PSP reports (see DODI 6025.17) and lessons learned to the Office of Assistant Secretary of Defense for Health Affairs (OASD(HA)), the Secretaries of the Military Services, the Surgeons General, the President of the Uniformed Services University of the Health Sciences, and all DOD MTFs.

c. The USAMEDCOM Staff Judge Advocate will provide legal interpretation of and guidance related to the contents and application of this regulation.

d. The USAMEDCOM Quality Management (QM) Directorate patient safety team (PST) will--

(1) Exercise broad oversight responsibility for development and implementation of the AMEDD PSP as delegated by TSG.

(2) Represent TSG as a member of various committees and working groups sponsored by OASD/HA, DOD, and other health care agencies.

(3) Educate and train MTF patient safety managers (PSMs) and other commander-selected individuals on all aspects of the AMEDD PSP.

(4) Provide advice, assistance, and ongoing feedback to the MTF staff in identifying and categorizing PS events, conducting aggregate reviews and RCAs, and developing appropriate action plans for process/system improvement.

(5) Provide tools to facilitate implementation of standardized PS processes and metrics to monitor and evaluate program compliance and effectiveness.

(6) Collect, maintain, analyze, and report aggregate PS data as required by the OASD/HA, DOD, and other agencies.

(7) Maintain the AMEDD PS database and submit MTF-specific information and reports regarding PS events, RCAs, action plans, and aggregate data to the AFIP PS registry per current DOD guidance.

(8) Monitor AMEDD PS trends and report the results to both internal and external sources, as appropriate.

(9) Publish "lessons learned" from reported AMEDD PS data to facilitate implementation of risk reduction strategies and promulgate evidenced-based best practices/safe practice methodologies (hereafter referred to as best/safe practices) throughout the AMEDD.

e. Regional Medical Command (RMC) commanders are/will--

(1) Responsible for effective implementation of the AMEDD PSP in their subordinate units.

(2) Assist the USAMEDCOM PSC with execution of the AMEDD PSP and PS training within the region.

f. The Commander, U.S. Army Medical Department Center and School, will--

(1) Facilitate programs of instruction that contain content relevant to the current AMEDD PSP and health care facility accreditation PS standards.

(2) Ensure that curriculum instruction emphasizes the responsibility that each member of the AMEDD has to participate in PS activities.

g. MTF commanders are/will–

(1) Responsible for effective implementation and compliance with AMEDD PS policy as defined in this regulation.

(2) Promote a culture that emphasizes cooperation and communication, encourages reporting of medical errors, focuses on error prevention rather than punishment, and improves medical systems and processes to overcome preventable errors.

(3) Designate an individual, with strong clinical and systems analysis background, as the PSM to direct the organization-wide PSP.

(4) Allocate the resources required to sustain a comprehensive, integrated PSP according to the provisions of this regulation.

(5) Promote strategies to encourage and facilitate staff identification and reporting of close calls/near misses and actual PS events.

(6) Designate membership of the PS committee/functional team responsible for support and oversight of all PS activities.

(7) Ensure all assigned staff are educated on AMEDD PSP components, roles/responsibilities, as well as effective communication, coordination, and teamwork techniques.

(8) Facilitate the education of MTF beneficiaries regarding their roles and responsibilities as partners in the health care process, to include the identification of PS-related issues.

h. Deputy commanders (e.g., deputy commander for clinical services (DCCS), deputy commander for nursing (DCN), or deputy commander for administration (DCA)) are/will--

(1) Responsible for oversight of the PSP and serve as chairperson of the interdisciplinary MTF safety committee/functional team (also see paragraph 9).

(2) Ensure that PSP activities are implemented, monitored, and evaluated for effectiveness according to this regulation.

(3) Support an organizational culture that emphasizes cooperation and communication, encourages reporting of potential and actual PS events, focuses on error prevention rather than punishment, and improves medical systems and processes to overcome preventable errors.

(4) Facilitate orientation and ongoing education of all staff regarding their roles and responsibilities.

(5) Promote support/assistance to staff members involved in a sentinel event (SE).

(6) Ensure that a qualified health care professional informs the patient or family member(s), according to the provisions of this regulation, when a PS event results in an unanticipated outcome of care.

i. Chief, department/service/clinic and management/supervisory staff will--

(1) Ensure PSP activities are implemented, monitored, and evaluated for effectiveness and actively participate in these processes.

(2) Support a culture at the department/service level that emphasizes cooperation and communication, encourages reporting of potential and actual PS events, focuses on error prevention rather than punishment, and improves medical systems and processes to overcome preventable errors.

(3) Facilitate orientation and ongoing education of all assigned staff regarding their roles and responsibilities in the PSP.

(4) Actively participate and facilitate the acknowledgement of reports and timely feedback to individuals (staff, patient, family, visitors) who report PS events.

(5) Facilitate coordination, integration, and implementation of inter/intradepartmental PS initiatives.

(6) Make recommendations for improving PS to the PSM and/or MTF PS committee/functional team.

(7) Promote support/assistance to staff members involved in SEs.

(8) Designate a qualified health care professional to inform the patient or family member(s), according to the provisions of this regulation, when a PS event results in unanticipated outcome of care.

(9) Ensure that staff members educate patients/family members on their roles and responsibilities related to the safe delivery of care.

j. Chief, Logistics and Pharmacy Division will, in addition to the responsibilities defined for department chiefs, facilitate notification of the PSM and appropriate department/service chiefs regarding all product liability complaints/recalls.

k. Patient safety manager. The PSM, or a similarly titled individual, is tasked with the coordination of the organization's PSP. The individual in this role may be expected to exercise broad oversight and to collaborate with various key staff to ensure the effective integration of the PSP functions by the organization. The PSM should be included in all activities involving PS issues. His/her membership on the MTF executive leadership team is encouraged. He/she will--

(1) Manage and facilitate the successful implementation and sustainment of the AMEDD PSP within the organization, according to this regulation.

(2) Provide expertise and guidance to staff members in the areas of risk assessment, prospective analyses, aggregate analyses, RCA, and the development and evaluation of action plans.

(3) Serve as the MTF liaison to the USAMEDCOM PSC.

(4) Coordinate, facilitate, and/or educate all MTF-assigned personnel on their roles and responsibilities in the PSP, to include reporting of all PS events, participating in MTF PS activities, and educating patients/families regarding all aspects of the safe delivery of care.

(5) Ensure that both MTF staff and beneficiaries are surveyed, according to current DOD guidance, to determine their perceptions of PS within their health care organizations. The PSC will provide the survey tool and instructions for its use.

(6) Implement a process to receive and centrally manage all PS event reports from clinical and administrative staff and/or patients and families.

(7) Evaluate each PS event report , either independently or as part of an MTF-level team and, based on the assigned safety assessment code (SAC), determine the appropriate level of review or analysis required.

(8) Acknowledge the receipt of PS reports and provide timely feedback to staff members who submit PS reports and/or plans for process/system improvements.

(9) Oversee the investigation of all SEs to ensure coordination of all data collection activities, completion of a thorough and credible RCA, development of an action plan, and required reporting through channels to the appropriate agency(ies).

(10) Ensure that PS action plans are implemented, evaluated for effectiveness, and communicated both internally and to the appropriate external organizational entities.

(11) Maintain the PS database and submit information and reports regarding PS events, RCAs, action plans, and aggregate data to the MTF PS committee/functional team and USAMEDCOM PSC.

(12) Review, aggregate, and analyze reports of all close calls, adverse events, and SEs--to include written findings and recommendations for improvements in systems and processes--to reduce the frequency and severity of patient harm.

(13) Serve as a member of the MTF PS committee/functional team and provide the committee, as well as all levels of staff, information regarding MTF, corporate, and nationwide PS alerts, updates, and initiatives.

(14) Present opportunities for improvement related to organizational risk assessment(s), with recommendations for identified risks, implementation plans, and follow-up activities to the MTF PS committee/functional team and USAMEDCOM PSC for action.

(15) Oversee the education of the beneficiary population regarding the role of patients/family members in the identification of PS-related issues.

(16) Ensure effective feedback to appropriate personnel on lessons learned and process/system improvements that have been or will be initiated.

l. The MTF safety and occupational health manager will serve as a voting member on the PS committee/functional team and serve as an active PST participant.

m. All MTF personnel will--

(1) Fully understand and take responsibility for their own roles in the PSP.

(2) Actively participate in creating a safe environment for themselves, peers, patients, and families by meeting organizational and professional standards, following identified best/safe practices, and proactively mitigate unsafe conditions or situations.

(3) Complete organization/unit-based orientation and participate in ongoing education, per organizational policy, related to the AMEDD PSP and all MTF PS activities.

(4) Voluntarily report all close calls/near misses, adverse events, and/or SEs.

(5) Initiate immediate steps to ensure patient and staff safety and secure any supplies/equipment that may have precipitated a PS event in order to prevent and/or mitigate future patient harm. If the event was caused or exacerbated by a supply or equipment problem, initiate a medical materiel complaint in accordance with AR 40-61. Submission of this complaint also satisfies the reporting requirement of the Safe Medical Devices Act of 1990.

(6) Educate patients/families in their roles and responsibilities to facilitate the safe delivery of care.

(7) Remain informed of recommended successful best/safe practices and safety alerts.

7. General.

a. PS involves a variety of clinical and administrative activities that health care organizations undertake to identify, evaluate, and reduce the potential for harm to beneficiaries and to improve the quality of health care. Effective medical/health care error reduction requires an integrated approach and a supportive environment in which patients, their families, organization staff, and leaders can identify, manage, and learn from actual and potential risks.

b. A successful PSP facilitates a non-punitive, interdisciplinary approach to decrease unanticipated adverse health care outcomes. The organizational focus is on continued learning about risks and mitigation strategies and reengineering systems/processes to reduce the chance of human error. The AMEDD fosters and supports an organizational environment that recognizes and acknowledges potential risks to PS and the occurrence of medical/health care errors. The PSP encourages medical error reporting in order to identify system or process failures and to enhance improvement strategies.

8. THE AMEDD PSP.

a. The goal of the AMEDD PSP is to reduce the chance that the adverse effects of human error will harm patients. By creating and promoting a culture in which staff willingly report actual and near-miss PS-related events without fear of disciplinary action, the AMEDD is encouraging these events to be freely identified. Once events have been identified, systems and processes can be analyzed and improved in order to

prevent future recurrence. Improved systems and processes result in a safer patient care environment.

b. The AMEDD PSP focuses on system and process design rather than on the individual involved in a given PS-related mishap. This paradigm is very different from that which currently prevails in the AMEDD and in the health care community at large. In the PS-conscious culture, when an error occurs the response is not to ask "who," but rather "why." This new paradigm can exist in light of other organizational expectations associated with risk management (RM), claims management, and review of potentially compensable events (PCEs) for which the Government may incur financial liability.

c. For all PCEs current regulatory guidance (AR 40-68) requires that an investigation be conducted to determine the cause(s) of the adverse event. In all paid medical malpractice claims, current legal statutes dictate that the professional practice of the significantly involved provider/professional will be reviewed to determine if the standard of care (SOC) was met. This RM review/reporting process involving the National Practitioner Data Bank and other regulatory agencies is likewise delineated in AR 40-68. While the PSP and RM processes are both protected under 10 USC 1102, each has its unique intent and focus.

d. A PS event that causes no patient harm requires no SOC determination. However, any PS event that results in patient harm, by definition, is a PCE. The risk manager will be notified of all PCEs and these will be managed according to the RM guidance in AR 40-68. Given the results of the QM investigation of the event, an SOC determination may be required. It may be appropriate and expedient to conduct the PS activities and SOC determination simultaneously, as separate but parallel activities. Competence-related information that arises through PS investigations will not be released outside the PSP except as noted in paragraph e below. The PSP will consider process/system issues, while the SOC determination reviews the individual's performance.

e. Although not a specific focus of the PSP, concerns about a specific provider's/professional's competence may arise. Competence relates directly to an individual and, as such, requires an evaluation of the provider's/professional's performance, not an evaluation of the health care system. Competence will be addressed through the organization's competence assessment, credentialing, and privileging processes. No individual competence-related information will be released outside the PSP, except as noted in paragraph f below. If the competency assessment processes are determined to require review and improvement, such recommendations by the PS committee/function may be appropriate.

f. The vast majority of errors are unintentional. No disciplinary action will be initiated against the individual(s) involved in an unintentional error. However, certain events, as noted below, do warrant administrative, disciplinary, or legal action. Should any of the following be discovered in the course of a PS event evaluation, the MTF commander

will be immediately informed of the circumstance; action taken is beyond the scope of the MTF PSP:

(1) Criminal activity (e.g., rape, assault and battery, homicide, etc.).

(2) Intentional unsafe acts due to gross negligence or reckless behavior.

(3) Alleged patient abuse of any kind.

(4) Impairment due to medical and psychological conditions including alcohol or other drug abuse.

9. THE MTF PS FUNCTION. Integration of all PS-related issues and processes under the auspices of a single committee/functional team is required. This reduces duplication of effort and enhances program efficiency.

a. Membership. The MTF PS committee/functional team membership will be multidisciplinary in its composition and include, as a minimum, selected leaders of the organization (e.g., the DCCS, DCN, DCA), or their respective representatives; the PSM; QM/performance improvement coordinator; risk manager; MTF safety and occupational health manager; as well as a cross-section of staff members who are empowered to influence organizational change in order to reduce harm to patients. Other participants may include the command sergeant major or representative; the patient representative; and a representative from pharmacy, logistics, infection control/preventive medicine, hospital education, and the office of the center judge advocate (OCJA)/office of the staff judge advocate (OSJA). Selected department/service chiefs, functional team leaders, and a community representative should also be considered for membership and/or consulted, as needed.

b. Chairperson. A senior, command-selected representative will chair the committee/function.

c. Committee/function minutes/reports.

(1) The PS committee/functional team minutes or reports will summarize the MTF's PS activities to include, as a minimum--

(a) Aggregation and analyses of all clinical and non-clinical-reported events, trends, and lessons learned.

(b) Actions necessary for organizational process/system improvements, as appropriate.

(c) Proactive PS error reduction activities.

(d) Progress related to organizational risk assessments, prospective analyses, and RCA action plan implementation and effectiveness, according to established timelines.

(2) The PS committee/functional team minutes or reports will be maintained according to AR 25-400-2.

(3) The PS minutes/reports are forwarded to the MTF executive committee. Recommendations associated with PS are considered and prioritized with other organizational system/process improvement actions, as appropriate.

10. THE PS ORGANIZATIONAL ASSESSMENT. PS encompasses complex, multidisciplinary processes. It is recommended that each health care organization systematically assess its high-risk organizational systems/processes to identify and prioritize safety improvement requirements. High-risk services/areas include, but are not limited to anesthesia, dialysis, emergency services, intensive care, obstetrics, the operating room, pharmacy, psychiatric treatment, radiology, and transfusion services.

a. PS organizational assessment facilitates the health care organization's evaluation of its current safety program and its various components as well as current policies and procedures, and, as a result of this evaluation, the MTF's PS improvement strategies can be appropriately prioritized.

b. Each MTF will perform an organizational PS assessment annually, according to its performance improvement priority schedule, using the measurement tool(s) provided by the USAMEDCOM PSC.

c. Other appropriate PS assessment activities may include reviewing internal (i.e., AMEDD organizations) and/or external data reports to identify high-risk areas for organizations of similar size and patient populations. External sources of information include, but are not limited to, the Joint Commission for the Accreditation of Healthcare Organization (JCAHO) SE report information; ORYX (see terms in glossary) core measures and performance data; occurrence reporting from State, national, and Federal sources; and the current literature.

d. Annual PS assessment activities may identify more than one organizational high-risk process improvement need. The PS committee/functional team will document and recommend to the MTF executive committee the high-risk process improvement priorities. The executive committee will select one high-risk process and ensure completion of a prospective analysis per current accreditation standards/methodologies and current USAMEDCOM guidance.

e. Any additional high-risk processes that have been identified will be prioritized and included in the MTF performance improvement annual plan. Formal analyses and improvement strategies for these process improvements will be completed per availability of appropriate organizational resources.

11. MANAGEMENT OF PS INFORMATION.

a. The focus of PS data collection and reporting in the AMEDD is to improve organizational systems and to provide the safest care possible to DOD beneficiaries. The PS data reporting processes will be standardized across the organization and will include and leverage existing corporate databases (i.e., MedMARx).

b. In an effort to examine trends in reported events across the AMEDD, each MTF will systematically collect USAMEDCOM-identified PS event core data elements as a minimum. Standardized core data elements to accurately capture PS-related events will allow each MTF and the USAMEDCOM the opportunity to track and trend aggregate data for effective analyses.

c. Data trend analyses will include, but not be limited to, the following:

(1) Medication errors and falls.

(2) Equipment malfunctions.

(3) Events categorized by severity per SAC methodology.

(4) Preventive/corrective interventions implemented.

d. Customized ad hoc queries and reports will be developed as directed by the USAMEDCOM PSC-published schedule. These may be requested from the PSM by internal MTF or external DOD sources.

e. Detailed data analyses of data using the query and reports capabilities will provide useful information to any level of management. This information will highlight the various contributing factors associated with PS events and facilitate decision-making regarding the specific process improvements required to prevent recurrence.

12. PS EVENT MANAGEMENT.

a. Event identification. A PS event is any incident that occurred (actual event) or almost occurred (close call/near miss) that caused or had the potential to cause harm to a patient. Identification and reporting of close calls and adverse events, including those that result from practitioner error, should be encouraged as an expectation of everyday practice. The three types of PS events include close calls/near misses, adverse events, and SEs.

(1) Close call/near miss. A close call is an event or situation that could have resulted in harm to a patient, but did not, either by chance or through timely intervention. The event was identified and resolved before reaching the patient. Such events have also been referred to as "near miss" incidents. Because close calls generally occur

more frequently than actual adverse events, proactive analyses of close calls provide a tangible opportunity to improve the system without having to experience an actual adverse event. Leaders should emphasize the value of close calls and encourage and acknowledge staff for reporting these opportunities for improvement.

(2) Adverse event. An adverse event is an occurrence associated with the provision of health care or services that may or may not result in harm to the patient/beneficiary. Adverse events may be due to acts of commission or omission. Incidents such as patient falls or improper administration of medications are also considered adverse events even if there is no harm or permanent effect on the patient.

(3) Sentinel event. An SE is an unexpected occurrence involving death, serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase, "or the risk thereof," includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and proactive response on the part of the organization.

b. Event documentation and internal reporting. Prevention of harm to patients is everyone's responsibility and reporting all potential and/or actual PS events is a performance expectation for all MTF-assigned staff. Anyone with knowledge of a PS event not only may, but should, report it.

(1) Immediate actions.

(a) Upon identification of an actual PS event, the staff member will immediately perform necessary health care interventions to protect and support the patient's clinical condition. The patient's attending physician and other physicians, as appropriate, will be contacted as soon as possible to report the incident and to provide an update on the patient's current clinical status.

(b) As appropriate to the event, the staff member will initiate all physician-directed orders and take other necessary health care interventions to contain the risk to others, and to preserve event-related materials that may require further investigation. Examples of physical information preservation include: removal and preservation of a blood unit for a suspected transfusion reaction; preservation of IV tubing, the fluid bag, and/or IV pump for a patient with a severe drug reaction from IV medication. Preservation of information also includes documenting the facts regarding the event in the patient's medical record according to organizational policy and procedure.

(c) If the PS event involves serious physical or psychological injury, unexpected death, or qualifies as an SE that is reviewable by the JCAHO, the appropriate department/service chief and the nursing supervisor will be notified immediately. If such PS events occur after hours, the administrative officer of the day will be notified immediately. Individuals notified will ensure proper notification of designated members of the MTF senior leadership.

(2) Documentation and internal reporting. Any individual in any department who identifies a potential (e.g., close call) or actual PS event will immediately notify his or her supervisor and will initiate an incident report . This report will contain concise, factual, objective, and complete details about the event. While explanation of the event is appropriate to include precipitating circumstances or reasons, speculation about factors that contributed to the event should be avoided.

(a) Incident reports will be forwarded to the staff member's unit, clinic, and/or department manager, as appropriate, within 24 hours of discovery of event or on the first duty day following a weekend or holiday. The manager/supervisor will review the document, add any additional relevant information, and forward it to the MTF PSM within 24 hours of receipt.

(b) The MTF PSM, or designee, will review all incident reports and assign a SAC (appendix B). In addition, the PSM will determine what specific actions are necessary to further evaluate SAC 2 events. If the PS event is a SAC 3, the PSM will immediately notify the MTF commander and a root cause analysis team (RCAT) will be chartered. The PSM will also enter the information from the incident report into the MTF PS database.

(c) If a PS event is an intentional unsafe act that results from gross negligence or possible criminal activity, the event shall be reported to the appropriate authorities for investigation. Such an event will not be managed under the auspices of the MTF PSP regardless of the SAC score. (See paragraph 8f for additional information.)

(d) Some events fall within the definition of both an adverse event and an intentional unsafe act. For example, an infant abduction would be both a crime and a JCAHO-reportable SE that requires an RCA. In cases that appear to be both an adverse event and an intentional unsafe act, primary authority and responsibility for dealing with the event belongs to the commander and risk manager; this event is beyond the scope of the PSP. The PSM will coordinate a review of the systems and processes implicated in the actual or potential intentional unsafe act, to include conducting an RCA, if applicable, but will defer to the separate command investigation with respect to the culpability of any person involved in the event.

(3) External reporting requirements. All incidents meeting the definition of an SE must be reported to the USAMEDCOM, and those events that meet the criteria for review by the JCAHO will be appropriately reported to that organization. External reporting of the PS event is the responsibility of the MTF commander (or his/her designee) and includes notification of--

(a) The USAMEDCOM PSC. All incidents meeting the definition of an SE and those that result in serious patient harm must be reported to the USAMEDCOM PSC within 72 hours of identification of the event. USAMEDCOM Form 732-R, Sentinel

Event Report Worksheet (appendix C), will be completed and transmitted by facsimile, electronic mail, or other electronic means of communication to the USAMEDCOM PSC. The MTF will also electronically notify its RMC of the occurrence of an SE.

(b) The JCAHO. All SEs that are reviewable by the JCAHO, as listed in paragraph 12b(3), must be reported to the JCAHO within 5 working days of the identification of the event. The appropriate documentation as required in current JCAHO guidance (**http://www.jcaho.org/sentinel/se_form.html**) will be completed and forwarded by facsimile transmission or commercial overnight delivery service to the JCAHO Office of Quality Monitoring, 1 Renaissance Boulevard, Oakbrook Terrace, IL 60181. No patient or caregiver identifiers will be used when reporting an SE to the JCAHO.

13. PS EVENT CLASSIFICATION. The PSM is responsible for reviewing and categorizing all reported PS events according to current DOD guidance as contained in this regulation. The SAC methodology categorizes each PS event using a 1-3 risk scoring scale as follows: 1 = low risk; 2 = moderate risk; and 3 = high risk. The SAC score methodology identifies the level of PS event analysis appropriate to the incident being considered.

a. SAC scoring of each PS event is based on the severity of the incident and its probability of recurrence. While there is some degree of subjectivity and individual judgment involved in this classification methodology, it provides organizations a standardized process for prioritizing actions and applying facility resources where there is the greatest opportunity to improve safety.

b. MTFs are encouraged to proactively evaluate and analyze any event, regardless of SAC score, that presents significant potential for future recurrence. It should be noted that the SAC score is extremely useful when evaluating close calls/near misses. Close calls generally occur more frequently than actual adverse events. Thus, proactive analyses of a close call provide an ideal opportunity to implement system or process improvements without having to experience an actual adverse event. With a close/near miss, the decision to charter a formal RCAT is at the discretion of MTF leadership.

(1) SAC 1 and 2 no-harm events. All SAC 1 and SAC 2 close calls and/or actual PS events with no harm to the patient will be entered into the MTF PS database. Monthly review and analyses for trends and/or process improvement opportunities will be conducted. The PS committee/functional team will review, prioritize, monitor, and track the effectiveness of all actions implemented.

(2) SAC 2 patient harm events. All SAC 2 events that result in harm to the patient will be reviewed by the PSM and the DCCS, or designee, to identify the appropriate level of event analysis warranted. If necessary, the USAMEDCOM PSC will be consulted to assist in identifying the best course of action for SAC 2 event management.

(3) SAC 3. SEs that are reviewable by the JCAHO and all other SAC 3 actual PS events require an RCA. For close calls/near misses with a potential SAC 3 score, the decision to charter an RCAT is at the discretion of the MTF leadership. SEs that are reviewable by the JCAHO include--

(a) All events resulting in an unanticipated death or major permanent loss of function (unrelated to the natural course of the patient's illness or underlying condition).

(b) Suicide in a 24-hour care setting.

(c) Infant abduction or discharge to the wrong family.

(d) Rape of a patient.

(e) Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities.

(f) Surgery on the wrong patient, the wrong body part, and/or the wrong site.

14. PS EVENT ANALYSIS. Event analysis assists in the discovery of the root causes and/or contributing factors associated with the PS event. Tracking and trending of data elements allows the PSM to identify familiar trends or circumstances so that system or process issues can be identified and improved. Levels of analyses include aggregate review and RCA.

a. Aggregate review analyses. Aggregate review consists of examining data elements for common trends or patterns within the group. The use of an aggregated review serves two important purposes. It allows wider applicability of the analyses (i.e., trends or patterns that were not noticeable in an individual case analysis become more obvious as the number of cases increases). In addition, it more clearly defines specific data elements in a recurring problem and encourages prudent use of the time and expertise of the MTF staff associated with evaluation and corrective action.

(1) Falls and medication errors in which no serious patient injury resulted will be analyzed on a quarterly basis using an aggregate review.

(2) Completed aggregate analyses will be forwarded to the USAMEDCOM PSC at the following address: Commander, USAMEDCOM, ATTN: MCHO-Q, 2050 Worth Road, Fort Sam Houston, TX 78234-6010, within 45 days following the end of the quarter. A follow-up after-action report identifying the effectiveness of all system and process improvements will be forwarded to the USAMEDCOM PSC 6 months after the aggregate analyses submission.

b. Root cause analysis. An RCA must be conducted and an action plan completed for all actual SAC 3 PS events and those that meet the definition of an SE. The MTF

commander, in consultation with the DCCS and PSM, will designate and formally charter an RCAT to conduct a thorough and credible RCA. The RCAT will conduct the RCA according to current USAMEDCOM guidance to facilitate standardization of data element collection and event analysis across the MHS.

(1) An RCA is the process for identifying the basic and/or contributing causal factor(s) associated with PS events. The review is interdisciplinary and includes those who are closest to the process, but typically not those directly involved in the specific event. (Note: Those individuals directly involved in the event will be consulted for event-related information.) The RCA focuses on systems and processes, not individual performance. The analysis asks "what" and "why" until all aspects of the process are reviewed and all contributing factors have been determined. It identifies changes that could be made in systems and processes to improve performance and to reduce the risk of adverse events, or the recurrence of close calls, with the ultimate goal of reducing and/or eliminating patient harm.

(2) If, in the course of conducting an RCA, it is determined the PS event is the result of an intentional unsafe act, deliberate gross negligence/reckless behavior, and/or possible criminal activity, the event shall be reported to the appropriate command authorities for investigation (paragraph 8f).

(3) The MTF risk manager and a legal advisor from the OCJA or the servicing OSJA will be notified of all SEs and may participate in the process of conducting the RCA, if appropriate.

c. RCA action plan. Once the RCA has been completed, a detailed action plan must be developed to enumerate the risk reduction strategies that the organization intends to implement to prevent the recurrence of similar events. The action plan should address responsibility for implementation, oversight, pilot testing (if appropriate), timelines, and the specific metrics to be employed in evaluating the effectiveness of the actions taken.

d. RCA and action plan review. The RCA and associated action plan for an SE will be submitted for review as follows:

(1) By the USAMEDCOM. A copy of the completed RCA and the action plan will be provided to the USAMEDCOM PSC within 45 calendar days of the MTF's discovery of the occurrence of an SE. Commercial overnight delivery service is authorized for this purpose.

(2) By the JCAHO. MTF commanders will select one of three alternatives to allow JCAHO review of the RCA and the action plan for a JCAHO-reviewable SE--

(a) Direct release of the RCA and action plan to the JCAHO using certified/return receipt mail or commercial overnight delivery service.

(b) Review of the RCA and the action plan delivered to JCAHO headquarters by MTF/dental treatment facility (DTF) staff then returned to the MTF/DTF immediately after review. A request for review by appointment must be received by the JCAHO at least 15 days prior to the due date for completion of the RCA and the action plan.

(c) An on-site visit by a specially trained surveyor to review the RCA and the action plan. A request for on-site review must be received by the JCAHO at least 15 days prior to the due date for completion of the RCA and the action plan.

e. Action plan follow-up review. Six months following the RCA submission, a follow-up after action report that addresses the effectiveness of the improvements implemented by the organization will be forwarded to the USAMEDCOM PSC, Commander, USAMEDCOM, ATTN: MCHO-Q, 2050 Worth Road, Fort Sam Houston, TX 78234-6010. A copy will be provided to the JCAHO, Office of Quality Monitoring, 1 Renaissance Boulevard, Oakbrook Terrace, IL 60181.

15. PS EVENT COMMUNICATION. Commanders and all MTF staff are reminded that all data compiled as part of the PSP are QA information protected under 10 USC 1102 and must be marked "Quality Assurance protected document 10 USC 1102; Unauthorized Disclosure Carries $5000 Fine." The authority for review of this protected information by the JCAHO and specifically authorized external agencies appears in 10 USC 1102.

a. The reporter of the PS event. Staff members and supervisors who submit PS event reports will receive timely feedback on the actions being taken as a result of their report. Prompt feedback to those who identify PS events has been credited in other reporting systems with being one of the cornerstones that establishes trust in the system. A timely response demonstrates the commitment on the part of the organization to the reporting effort. The nature of feedback to the individual can range from a simple acknowledgement that the event is under consideration to providing information about the corrective action that is planned/has been accomplished. This communication openly confirms the importance of the staff member's efforts to participate actively in organizational performance improvement.

b. Staff members involved in the PS event. Any staff member reporting and/or directly involved in a PS event that caused patient harm will receive support and assistance from his/her supervisor to facilitate the staff member's professional and emotional needs related to the PS event. Management efforts and activities will focus on improving the systems and processes that may have contributed to the PS event rather than disciplining those involved.

c. Patient/family affected by the event. In cases involving an unanticipated outcome of care, a qualified health care provider will inform the patient and/or his/her family member(s). This information is provided as a matter of policy and does not affect any

rights or obligations in legal or administrative proceedings. Under no circumstances will QA-protected information be released or provided to the patient/family member.

(1) The MTF commander, or designee, is responsible to ensure that provider and patient/family member communication takes place. To ensure continuity, the initial disclosure of information and subsequent discussions with the patient and/or family should be handled, whenever possible, by the primary care manager or attending physician responsible for the patient's overall care. During the initial communication, and at subsequent planned discussions, at least one other hospital staff member should be present. For discussions anticipated to be complex or difficult, the patient/family member may have another individual with them for support. The designated primary communicator will document in the patient's medical record what was communicated to the patient/family, the patient/family member's response, and any other pertinent discussion.

(2) In most cases, facts surrounding the PS event that affect the patient can and should be disclosed to the patient/family member by the provider.

(3) Any specific questions relative to disclosure of information associated with unanticipated adverse outcomes should be referred to the MTF OCJA or OSJA.

d. Safe/best practices and lessons learned. To facilitate a successful AMEDD PSP, it is imperative that all levels of personnel (MTF/corporate) learn from PS-related incidents by being informed of the system/process contributing factors that resulted in patient harm.

(1) The MTF PSM will provide feedback to all levels of MTF staff on reported PS events and lessons learned. These include PS improvement strategies and best/safe practices to be implemented at the unit/clinic level to prevent recurrence of similar events in the future.

(2) The USAMEDCOM PSC and AFIP will identify trends and opportunities for improvement, to include safe/best practices and implementation strategies identified through corporate and MHS PS event analysis. This information will be distributed using the USAMEDCOM PSC and AFIP web sites and other appropriate communication mechanisms.

(3) The MTF PSM will also receive regular electronic and telephonic feedback and support from the USAMEDCOM PSC regarding SEs, RCAs, aggregate analyses, and the development and evaluation of RCA action plans.

16. PS EDUCATION AND TRAINING.

a. MTF staff. All assigned personnel will receive PS education and training during their initial hospital orientation and on an annual and as-needed basis, regarding job-related aspects of PS and staff-specific roles and responsibilities to actively support PS policy. PS-related topics include, but are not limited to--

(1) An overview of the AMEDD PSP and MTF program execution.

(2) Roles and responsibilities in reporting PS events.

(3) Patient education requirements.

(4) Effective communication and teamwork strategies.

b. Patients/family members. Health care beneficiaries and family members will receive education about their role in helping to facilitate the safe delivery of care. Topics will include general information about the PSP and the ways beneficiaries/family members can effectively participate in PS.

c. RCAT members. Personnel selected to serve on an RCAT will receive "just-in-time" training which includes RCAT process guidance and team rules, effective interview techniques, and the appropriate use of RCA tools (e.g., flow charts, cause and effect diagrams).

17. PS METRICS. The effectiveness of the PSP will be evaluated at all levels using standardized metrics. Measuring the progress of this newly implemented program is key to its success as a dynamic, meaningful program. As the PSP matures, the goals will be updated to ensure that different aspects of the program are addressed according to current corporate guidance. As the AMEDD PSP evolves, the evaluation metrics are likewise expected to change. The current PS metrics are listed in appendix D. These metrics, as identified, relate to the PSP goals at the MTF level for the first year of the program.

18. PS REPORTING. Internal and external reporting related to the PSP includes--

a. The MTF executive committee.

(1) Minutes/reports from the PS committee/functional team will be submitted to the MTF executive committee per established MTF guidelines. These minutes/reports will summarize the results of MTF organizational/high-risk area assessments, PS events, and progress on all action plans implemented as a result of a PS event analysis. The PS committee/functional team will also provide recommendations to the MTF leadership for improvements to specific PS processes, PS initiatives, and other organizational changes, as appropriate.

(2) The annual Clinical Quality Management Program report submitted for review by the executive committee will include a PSP evaluation and summary of the MTF organizational/high-risk area assessments, PS events, and progress on all action plans implemented as a result of a PS event analysis. This report will be forwarded through the RMC commander to USAMEDCOM PSC with internal copy provided to the USAMEDCOM PSC.

b. The USAMEDCOM PSC. A quarterly PS report utilizing the USAMEDCOM-provided format will be forwarded electronically to the USAMEDCOM PSC. The report will include requested aggregate data and summarize the results of all MTF PS event analysis, progress on action plans implemented, and the effectiveness of these actions, as appropriate. The quarterly report is due NLT 45 days after the end of each fiscal year quarter.

19. CONFIDENTIALITY OF MEDICAL QUALITY ASSURANCE INFORMATION. As with other medical QA documents, any information, records, reports, minutes, and other documents directly associated with PS activities are protected under 10 USC 1102. In discussing medical information with family members, MTF personnel shall also comply with other applicable restrictions on nonconsensual disclosures, including those under the Privacy Act, 5 USC 552a; DOD Regulation 5400.11-R ; and Service regulations. As a general rule under the Privacy Act, information regarding a patient's condition shall not be provided to others without the patient's consent.

Appendix A

References

Section I
Required Publications

AR 25-400-2
The Modern Army Recordkeeping System (MARKS)

AR 40-61
Medical Logistics Policies and Procedures

AR 40-68
Quality Management

DOD Directive 6040.37
Confidentiality of Medical Quality Assurance (QA) Records, 9 July 1996

DOD Instruction 6025.17
Military Health System Patient Safety Program, 16 August 2001

DOD Regulation 5400.11-R
Department of Defense Privacy Program

United States Code (USC), Title 10, Section 1102 (10 USC 1102)
Confidentiality of Medical Quality Assurance (QA) Records 1987

Unnumbered publication
Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Accreditation Manual: Comprehensive Accreditation Manual for Hospitals (2001)

Section II
Related Publications

Floyd D. Spence Defense Authorization Act for Fiscal Year 2001
(Sections 742 and 754)

Institute of Medicine Report #1
To Err is Human: Building a Safer Health System. Washington, DC: National Academy Press (1999)

Institute Of Medicine Report #2
Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC: National Academy Press (2001)

Marx, David
Patient Safety and the "Just Culture": A Primer for Health Care Executives. Medical Event Reporting System for Transfusion Medicine. New York: Trustees of Columbia University (2001)

Spath, Patrice L.
Error Reduction in Health Care–A Systems Approach to Improving Patient Safety. San Francisco: Jossey-Bass (2000)

MEDCOM Reg 40-41

Appendix B

Patient Safety Program
Safety Assessment Code Matrix

Severity Categories

Key factors for the severity categories are: extent of injury; length of stay; and level of care required for remedy. The four categories below apply to actual adverse events.

For actual close calls/adverse events, assign severity based on the patient's actual condition. Some incidents that occur may have such an overwhelming potential for a catastrophic event that an RCA will also be necessary, but that determination will be left to the discretion of the MTF.

Catastrophic	Major
Patients with actual:	**Patients with actual:**
Death or major permanent loss of function (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying condition (i.e., acts of commission or omission). Suicide (inpatient or outpatient). Rape. Hemolytic transfusion reaction. Surgery/procedure on the wrong patient or wrong body part. Infant abduction or infant discharge to the wrong family. Death or major permanent loss of function that is a direct result of injuries sustained in a fall, or associated with an unauthorized departure from an around-the-clock treatment setting, or the result of an assault or other crime.	Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying conditions (i.e., acts of commission or omission). Disfigurement. Surgical intervention required. Increased length of stay or level of care of 3 days or more.
Moderate	**Minor**
Patients with actual:	**Patients with actual:**
Increased length of stay or higher level of care for less than 3 days.	No increased length of stay or increased level of care.

Probability of Recurrence

Like the severity categories, the probability of recurrence applies to actual adverse events and close calls.

In order to assign a probability rating for an adverse event or close call, it is ideal to know how often it occurs at your facility. Sometimes, the data will be easily available because it is routinely tracked (e.g., falls with injury, medication errors, etc.). Sometimes, getting a feel for the probability of events which are not routinely tracked will mean asking for a quick or informal opinion from staff most familiar with those events. Sometimes it will have to be your best educated guess.

High – Likely to occur immediately or within a short period of time.
Medium – Likely to occur several times in 1 to 2 years.
Low –May happen at intervals greater than 2 years.

How the SAC Matrix Looks

	SEVERITY			
PROBABILITY	Catastrophic	Major	Moderate	Minor
High	3	3	2	1
Medium	3	2	1	1
Low	3	2	1	1

How The SAC Matrix Works

When a severity category is paired with a probability category for either an actual event or close call, the result is a ranked matrix score (3 = highest risk, 2 = intermediate risk, 1 = lowest risk). These ranks, or SACs, can then be used for comparative analyses and for deciding who needs to be notified about the event.

Notes

1. All known reporters of events, regardless of SAC score (1, 2, or 3), will receive appropriate and timely feedback.

2. The PSM (or designee) will refer adverse events or close calls (related solely to staff, visitors, or equipment/facility damage) for assessment and resolution to relevant facility experts or services on a timely basis.

3. A quarterly aggregated analyses may be used for two types of calls (this includes all events or close calls other than actual SAC 3s, since all actual SAC 3s require an individual RCA). These two types are falls and medication errors. The use of aggregated analyses serves two important purposes. First, greater utility of the analyses (i.e., trends or patterns not noticeable in individual case analysis) are more likely to show up as the number of cases increases. Second, it makes wise use of the RCA team's time and expertise.

Of course, the facility may elect to perform an individual RCA rather than aggregated review on any adverse event or close call that they think merits that attention, regardless of the SAC score.

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*29 CFR 1960.70 requires each Federal agency to notify the Occupational Safety and Health Administration within 8 hours of a work-related incident which results in the death of an employee or the inpatient hospitalization of three or more employees.

Appendix C

Sentinel Event Report Worksheet (MEDCOM Form 732-R)

SENTINEL EVENT REPORT WORKSHEET

For use of this form see MEDCOM Reg 40-41

SECTION I - DEMOGRAPHICS

1. MEDICAL TREATMENT FACILITY (Name and Location)		2. CASE NUMBER
3. MTF POC *(Last Name, First, MI)*	4. TELEPHONE and FAX NUMBERS	5. DATE *(dd-mmm-yy)*

SECTION II - EVENT IDENTIFICATION

DIRECTIONS: All incidents meeting the current Joint Commission on Accreditation of Healthcare Organizations (JCAHO) definition of a sentinel event will be reported to the USAMEDCOM, Patient Safety Center (PSC). This form will be completed and transmitted by facsimile (FAX) to 210-221-7118, or other electronic means. Other requirements of the JCAHO related to a sentinel event will also be followed.

6. TYPE OF EVENT *(Check all that apply):*

☐ Unanticipated death or, ☐ Major permanent loss or, ☐ Serious Physical injury or ☐ Serious psychological injury not related to natural course of patient's illness or underlying condition.
Preliminary information indicates this is related to ☐ Anesthesia ☐ Delay in Treatment/Transfer ☐ Laboratory
☐ Equipment ☐ Restraints ☐ Fall ☐ Environment of Care (e.g., Fire, Hazardous Material, Medical Gas, Security, Utilities)
☐ Operative/Other Invasive Procedure ☐ Medication ☐ Obstetric Complication
☐ Other (Specify) _____

☐ Suicide in a 24-hour facility

☐ Infant abduction, or ☐ Infant discharged to wrong family.

☐ Rape

☐ Hemolytic transfusion reaction due to administration of blood or blood products having major blood group incompatabilities

☐ Surgery on the wrong patient, ☐ Surgery on the wrong site (side/level/part), or ☐ The wrong surgery/procedure performed

☐ A close call (near miss), a recurrence of which presents a significant chance of a serious adverse outcome

☐ Other, *(Please explain briefly)* _____

SECTION III - TIMELINES

7. REPORTING REQUIREMENTS. From discovery date of incident the following will apply:

a. 72 hours to report incident to USAMEDCOM PSC.

b. Five (5) days to report to JCAHO.

c. 45 days to transmit completed root cause analysis (RCA) and action plan to the JCAHO and USAMEDCOM PSC.

8. RECORD OF EVENTS.

DATE	ACTION
	a. Incident identified.
	b. Root Cause Analysis Team Chartered.
	c. Incident reported electronically or telephonically to USAMEDCOM PSC.
	d. Regional Medical Command (RMC) notified.
	e. Initial report of incident to JCAHO *(If applicable)*.
	f. RCA and action plan to USAMEDCOM PSC.
	g. RCA and action plan to JCAHO *(Select one)*:
	☐ Certified mail/overnight delivery
	☐ Review at JCAHO central office
	☐ On-site visit by JCAHO representative

SECTION IV - USAMEDCOM ACTION

9a. USAMEDCOM ACTION OFFICER *(Name)*	9b. USAMEDCOM LOG NUMBER

10. FOLLOW-UP WITH MTF.

DATE	ACTION

The information placed on this form is confidential and privileged IAW 10 U.S.C. 1102
UNAUTHORIZED DISCLOSURE CARRIES A $5,000 FINE.
DO NOT FILE OR REFER TO THIS FORM IN PATIENT RECORD. REPORT EVENT TO SUPERVISOR/DEPARTMENT CHIEF IMMEDIATELY.

MEDCOM FORM732-R (MCHO) DEC 01 MC V1.00

Appendix D

Patient Safety Program Metrics

Quantitative standards will be established to evaluate the effectiveness of the PSP on an ongoing basis. Each facility should define such metrics in accordance with baseline data that have been obtained either through the PSC or through local data analyses. As the program evolves and matures, the goals/objectives of the program will change. Metrics used to measure program effectiveness should be modified to reflect these changes. As a minimum, each facility will implement the following during the first year of PSP implementation to measure program effectiveness.

(1) The AMEDD PSP is in place (i.e., 100 percent compliance) as evidenced by the following activities. The organization is completing the MEDCOM PSP-identified PS risk assessment(s), establishing the PS database, conducting an aggregate review, and performing a prospective analysis and RCA.

(2) The organization is actively transitioning to a culture of safety and openly discussing PS issues as evidenced by a median score in the climate survey reassessment of 10 percent over the individual MTF baseline.

(3) There is a 10 percent increase in close call/near miss reporting each quarter after the first quarter (e.g., the baseline) to be measured by the number of close calls/near misses reported over the total number of PS events.

(4) One system improvement and/or safe/best practice is identified, implemented, and monitored for effectiveness.

GLOSSARY

Section I
Abbreviations

AMEDD
Army Medical Department

AFIP
Armed Forces Institute of Pathology

DCA
deputy commander for administration

DCCS
deputy commander for clinical services

DCN
deputy commander for nursing

DOD
Department of Defense

DODI
Department of Defense Instruction

DTF
dental treatment facility

JCAHO
Joint Commission for Accreditation of Healthcare Organizations

MHS
military healthcare system

MTF
military treatment facility

OASD(HA)
office of Assistant Secretary of Defense for Health Affairs

OCJA
office of the center judge advocate

OSJA
office of staff judge advocate

PCE
potentially compensable event

PS
patient safety

PSC
Patient Safety Center

PSM
patient safety manager

PSP
Patient Safety Program

PST
patient safety team

QA
quality assurance

QM
quality management

RCA
root cause analysis

RCAT
root cause analysis team

RM
risk management

RMC
regional medical command

SAC
safety assessment code

SE
sentinel event

SOC
standard of care

TSG
The Surgeon General

USAMEDCOM
U.S. Army Medical Command

USC
United States Code

Section II
Terms

Action plan
The end product of an RCA that identifies the risk reduction strategies the organization intends to implement to prevent the recurrence of similar adverse events in the future.

Actual event
A situation or circumstance that did occur either with or without harm to the patient.

Adverse event
An adverse event is an occurrence or condition associated with the provision of health care or services that may or may not result in harm to the patient/beneficiary. Adverse events may be due to acts of commission or omission. Incidents such as patient falls or improper administration of medications are also considered adverse events even if there is no harm or permanent effect on the patient.

Aggregate
To combine standardized data and information collected over time.

Aggregate review
The process of analyzing recurring incidents, events, or close calls (near misses) for trends and patterns. This information is utilized by the organization for process improvement interventions.

Close call
A close call is an event or situation that could have resulted in harm to a patient, but did not, either by chance or through timely intervention. The event was identified and resolved before reaching the patient. Such events have also been referred to as "near miss" incidents. Because close calls generally occur more frequently than actual adverse events, proactive analysis of close calls provides tangible opportunity to improve the system without having to experience an actual adverse event. Leaders should emphasize the value of close calls and encourage and acknowledge staff for reporting these opportunities for improvement.

Contributing factors
Additional reasons, not necessarily the most basic reasons, for an event to be less than ideal, as planned, or as expected. Contributing factors may apply to individuals, systems operations, or the entire organization.

Data
Material facts or clinical observations that have not been interpreted.

Evaluation
Analysis of collected, compiled, and organized data pertaining to important aspects of care. Data are compared with predetermined, clinically valid criteria; variations from criteria are determined to be acceptable or unacceptable; and problems or opportunities to improve care are identified.

Gross negligence
See Reckless conduct.

Intentional unsafe act
Any alleged or suspected deliberate act or omission by a provider, staff member, contractor, trainee, or volunteer pertaining to a patient that involves--a criminal act; a purposefully unsafe act; patient abuse; or an event caused or affected by drug or alcohol abuse. Intentional unsafe acts are matters for law enforcement, the military or civil service disciplinary systems, or an administrative investigation, and are not within the definition of an adverse event.

Near miss
An event or situation that could have resulted in harm to a patient but did not, either by chance or through timely intervention. The event was identified and resolved before reaching the patient. Such events have also been referred to as "close call" incidents.

ORYX
A JCAHO initiative that integrates outcomes and other performance measurement data into the accreditation process.

Patient safety event
An incident or error that occurred (actual event), or almost occurred (close call/near miss), that caused, or had the potential for causing, harm to a patient.

Quality improvement
An approach to the continuous study and improvement of the processes of providing health care services to meet the needs of individuals and others. Synonyms include continuous quality improvement, continuous improvement, organization-wide PI, and total quality management.

Rape
Sexual intercourse by a person, executed by force and without consent of the victim. It may be committed on a victim of any age. Any penetration, however slight, is sufficient to complete the offense. "Any person subject to this chapter who commits an act of sexual intercourse by force or without consent, is guilty of rape." (Article 120, UCMJ)

Reckless conduct
Involves conscious disregard of risk. Also referred to as gross negligence. Reckless conduct differs from "negligent conduct" in intent. Negligence is the failure to recognize a risk that should have been recognized while reckless conduct is a conscious disregard of a known risk. NOTE: The legal definitions may vary slightly.

Risk assessment
A method used to proactively evaluate the probability of a patient safety event in order to minimize the risk of the event actually occurring.

Risk management
Clinical and administrative activities that organizations undertake to identify, evaluate, and reduce the risk of injury to patients, staff and visitors, and the risk of financial loss to the organization. It involves identification of risk potential, prevention of risk exposure, and the management of real or potential adverse incidents and medical malpractice claims.

Root cause
The most basic reason that a situation did not turn out ideally, as planned, or as expected.

Root cause analysis
A process for identifying the basic or contributing causal factor(s) associated with an adverse event or close call. The review is interdisciplinary and includes those who are closest to the process. It focuses on systems and processes, not individual performance. The analysis asks "what" and "why" until all aspects of the process are reviewed, and all contributing factors have been determined. It identifies changes that could be made in systems and processes to improve performance and reduce the risk of adverse events or recurrence of close calls.

Root cause analysis team (RCAT)
The group identified by the MTF/DTF commander to develop the RCA and Action Plan. The RCAT should include leaders of performance improvement/QM, RM, nursing and patient care services; the medical staff; the department head or supervisor of the area in which the event occurred; administrative staff (e.g., DCA, RM, MTF Safety); a Staff Judge Advocate representative; and others as necessary depending on the event. RCAT members will be trained and knowledgeable in the SE process.

Safety assessment code (SAC) matrix
A risk assessment tool that considers the severity of an adverse or near miss event together with the probability of the event's recurrence. The score, or SAC, assigned to the event determines the type of action that should be taken to address the event (i.e. RCA, intense analysis, or no action). See appendix B.

Sentinel event
A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof that is not related to the natural course of the patient's illnesses or underlying condition. Serious injury specifically includes loss of limb or function. The phrase, "or the risk thereof," includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and proactive response on the part of the organization.

The proponent of this publication is the Quality Management Directorate. Users are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) to Commander, U.S. Army Medical Command, ATTN: MCHO-Q, 2050 Worth Road, Fort Sam Houston, TX 78234-6010.

FOR THE COMMANDER:

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Appendix D

Patient Safety Climate Survey

Thursday July, 2001 - 10:40:50 AM

This is an anonymous and completely voluntary survey designed to obtain honest answers to patient safety and incident reporting issues. It takes about 4-6 minutes to complete. The AMEDD Patient Safety Program's goal is to improve incident reporting through the adoption of a non-punitive reporting approach. Your truthful answers to the following questions will assist in this goal. **Thank you** for taking time out of your busy day to complete this important survey!

Part I - Demographic Information

Please select your Position and Location from the select boxes below.

Position: Select Position **Facility:** Select Facility

Part II - Survey Response

Listed below are statements of how people feel about various factors that affect patient safety and the reporting of errors. Patient safety is defined as actions undertaken by individuals and organizations to protect patients from being harmed by the effects of health care services. A near miss/close call is an event that could have resulted in harm to a patient, but did not, ether by chance or through timely interventions. Sentinel events are unexpected occurrences involving death or serious physical or psychological patient injury.

Please mark in the appropriate box to indicate whether YOU Strongly Disagree, Disagree, Agree, or Strongly Agree with each statement.

Strongly Disagree - 1	Disagree - 2	Agree - 3	Strongly Agree - 4

MOST PEOPLE IN THIS MTF...

		1	2	3	4
1.	Are willing to report clinical errors.	◉	○	○	○
2.	Agree that patients also play a role in preventing clinical errors and mishaps.	○	◉	○	○
3.	Fear there will be negative consequences associated with reporting clinical errors.	○	○	○	○
4.	Provide support for those who make unintentional clinical errors.	○	○	○	○
5.	Cooperate with one another to resolve patient safety issues.	○	○	○	○
6.	Are not willing to admit to patients when they make errors.	○	○	○	○

7.	Regularly report all clinical errors.	○	○	○	○
8.	Feel comfortable reporting unsafe patient conditions to the supervisor.	○	○	○	○
9.	Believe things can be done to reduce the likelihood of a clinical mishap.	○	○	○	○
10.	Do not believe the organization's senior leaders place a high priority on patient safety.	○	○	○	○
11.	Believe most clinical errors are preventable.	○	○	○	○
12.	Are willing to discuss what went wrong when a sentinel event occurs.	○	○	○	○
13.	Often blame others for their own mistakes related to patient safety.	○	○	○	○
14.	Are willing to report near miss/close call patient incidents.	○	○	○	○
15.	Believe their immediate supervisors are committed to improving patient safety.	○	○	○	○
16.	Hesitate to change practice habits to improve patient safety.	○	○	○	○
17.	Are willing to share information about clinical errors and what caused them.	○	○	○	○
18.	Regularly report clinical errors whether or not the patient was harmed.	○	○	○	○

19. Believe MEDCOM leadership is committed to improve patient safety

20. What is your perception of the number one Patient Safety issue at your facility? (Please enter your answer in the textbox below.) (Note. Please limit response to 1,000 characters, or less.)

Submit Survey

Appendix E

Dear Expert Panel:

Thank you for participating in this evaluation of our "Patient Safety Climate Survey." We are asking you to help us assess the content of the instrument by rating the validity of each of the survey items. The validity of any instrument is how well it represents the characteristics the developers intend to measure. In this survey, we hope to conduct a brief assessment of the climate within an organization around the issue of patient safety and reporting errors. Climate would include how most people in the organization view reporting their own and other's errors; how cooperative people are in developing solutions; and the attitudes about patient safety of people in leadership positions. Any suggestions for revision or elimination of items would be appreciated. Attached is the draft survey. Please review the instructions to the respondents and you may write comments about the instructions and the items directly on this page. Please return both pages by e-mail or fax: (210) 221-7118. If there are any questions please contact Lynne Connelly by e-mail or at (210) 221-8526. Thank you for your help.

Please rate each of the survey items on the following 4-point rating scale:

Rating for Content Validity

1- Not a relevant item
2- Unable to assess relevance of item without revision
3- Relevant item but needs minor alteration
4- Very relevant item

Most people in this MTF...

	ITEM	1	2	3	4
1.	Are open to hearing how their actions affect patient safety.				
2.	Can listen to feedback from others without getting defensive.				
3	Fear there will be negative consequences associated with reporting errors.				
4.	Don't retaliate against those who make mistakes				
5.	Believe even competent, well-trained professionals make mistakes.				
6.	Are not willing to admit to patients that caregivers sometimes make mistakes.				
7.	Cooperate with one another to resolve problems.				
8.	Regularly report all patient incidents.				
9.	Feel comfortable reporting unsafe conditions to their supervisors.				
10.	Believe things can be done to reduce the likelihood of a medical mishap.				
11.	Do not believe the organization's leaders place a high priority on patient safety.				
12.	Often blame others for their mistakes.				
13.	Believe a medical accident could occur in this MTF.				
14.	Are willing to discuss what went wrong when a significant patient incident occurs.				
15.	Believe most patient incidents are preventable.				
16.	Agree that patients play a role in preventing medical mistakes and mishaps.				
17.	Believe the organization's leaders are committed to improving patient safety.				
18.	Are not willing to change old habits to improve patient safety.				
19.	Are willing to share information about errors they have made and the contributing factors.				

Patient Safety Climate Survey

Listed below are statements of how people feel about various factors that influence patient safety and the reporting c errors. Patient safety is defined as actions undertaken by individuals and organizations to protect patients from being harmed by the effects of health care services. Please mark in the appropriate box to indicate YOUR level of agreement with each statement.

Most people in this MTF...	**Strongly Agree**	**Agree**	**Disagree**	**Strongly Disagree**
1. Are open to hearing how their actions affect patient safety.				
2. Can listen to feedback from others without getting defensive.				
3. Fear there will be negative consequences associated with reporting errors.				
4. Don't retaliate against those who make mistakes.				
5. Believe even competent, well-trained professionals make mistakes.				
6. Are not willing to admit to patients that caregivers sometimes make mistakes.				
7. Cooperate with one another to resolve problems.				
8. Regularly report all patient incidents.				
9. Feel comfortable reporting unsafe conditions to their supervisors.				
10. Believe things can be done to reduce the likelihood of a medical mishap.				
11. Do not believe the organization's leaders place a high priority on patient safety.				
12. Often blame others for their mistakes.				
13. Believe a medical accident could occur in this MTF.				
14. Are willing to discuss what went wrong when a significant patient incident occurs.				
15. Believe most patient incidents are preventable.				
16. Agree that patients play a role in preventing medical mistakes and mishaps.				
17. Believe the organization's leaders are committed to improving patient safety.				
18. Are not willing to change old habits to improve patient safety.				
19. Are willing to share information about errors they have made and the contributing factors.				

Appendix F

10 Feb 02

Code Book 1

1. Accountability (abbreviation: acct)—the accountability of hospital staff in caring for patients

2. Attention to detail (atd)—need for attention to detail by the hospital staff in caring for patients.

3. Acuity-high (acu-hi)-- high acuity of patients leading to chance for errors.

4. Acuity-Low (acu-lo)—low acuity that leads to few chances to perform selected procedures.

5. Blood transfusion (bld)—errors related to the use of blood transfusions.

6. Communications (com)—errors related to lack of communication between health care providers or a statement about the need for communication.

7. Continuity of care (c of c)—the lack of continuity leading to errors.

8. Use of contract personnel (contract)—leads to errors

9. Culture of blame (cul)—blaming providers or providers fearing to report errors.

10. Documentation errors (docu)—errors related to documentation of patient care and medical records.

11. Falls (falls)—patient falls in the hospital or in the parking lot,

12. Follow-up (fol-up)—follow-up of care/lab results/etc. by providers.

13. Equipment (equip)—errors or problems related to equipment, also outdated equipment.

14. Facility (fac)—the physical plant of the MTF, especially old or problematic.

15. Funding (fund)—lack of adequate funding to run the MTF.

16. Fire (fire)—problems related to potential fire in the MTF.

17. General statements about patient safety (gen)—as stated.

18. Geriatric patients (geri)—errors related to the care of geriatric patients.

19. Housekeeping (house)—errors related to housekeeping or the lack of adequate housekeeping.

20. Infection control (infect)—nosocomical infection or other infection control issues.

21. Inexperience of personnel (inexp)- inexperience of hospital personnel that leads to incompetence and/or errors.

22. Lack of time (lot)—personnel not having enough time to adequately care for patients.

23. Lack of training/education (lotx)—lack of appropriate training or education for personnel.

24. Laboratory errors (lab)—errors related to lab such as mislabeling specimens.

25. Medication errors (med)—errors related to medications. Also indicate type: dispensing, administration, 5 rights, follow-up, number of meds, drug interactions, patient knowledge, computer systems).

26. Lack of supervision (lacsup)—lack of supervision of hospital personnel.

27. Leadership (lead)—negative leadership in the organization.

28. Miscellaneous (misc)—miscellaneous comments that don't fit in the other codes and are not frequent comments.

29. Missed diagnosis (miss dx)—patient has not been diagnosed properly.

30. Not flowing instructions/orders (not follow)—as written.

31. Needle sticks (needle)—as written.

32. Patient education (pt ed)—lack of proper patient education.

33. Paperwork (paper)—too much paperwork.

34. Patient identification (pt id)—not identifying the correct patient.

35. Parking lot (park)—problems in the parking lot of the MTF.

36. Policy (pol)—policies including TriCare.

37. Poor attitude of staff (poor att)—staff with poor attitudes.

38. Positive statement about patient safety at the MTF (pos)

39. Resistance to change (resist)—from hospital staff.

40. Restraint (restr)-errors related to restraints.

41. Reporting of errors (report er)—lack of reporting of errors or problems with reporting of errors.

42. Specific to Facility (specif)—comment is unique to the MTF.

43. Safety of staff (saf staf)—issues related to staff safety.

44. Security (secur)—security of the MTF.

45. Scope of practice (s of p)—issues related to scope of practice.

46. Staffing (staf)—lack of appropriate staffing in the MTF.

47. Stress (stres)—stress experienced by hospital personnel leading to errors.

48. Taskings (task)—additional taskings including deployments.

49. Transfer or transport of patients (trans)—errors associated with the transfer or transport of patients.

50. Turnover of staff (turn) increase in turnover leading to erros.

51. Unattended or uncontrollable children (child)—with siblings or parents.

Appendix G

22 Feb 02

Code Book 2

1. Accountability (abbreviation: acct)—the accountability of hospital staff in caring for patients. This includes need for attention to detail by the hospital staff in caring for patients.

2. Continuity of care (c of c)—the lack of continuity of care leading to errors. Includes patient being seen by multiple providers, inappropriate use of ER, problems with follow-up of care/lab results/etc. by providers.

3. Children (child)—accompanying patient on appointment and left unattended or parents do not control children's behavior.

4. Communications (com)—errors related to lack of communication between health care providers or with patients, or a statement about the need for communication.

5. Culture of blame (cul)—blaming providers or providers fearing to report errors. Includes negative comments about leadership in the organization and respondents' perceptions of resistance to change from hospital staff.

6. Documentation errors (docu)—errors related to documentation of patient care and medical records. Includes complaints about the volume of documentation required.

7. Equipment (equip)—errors or problems related to equipment, also outdated equipment. Includes staff lack of competence on appropriate use of equipment.

8. Facility (fac)—the physical plant of the MTF, especially old or problematic. This includes problems with parking and safety in parking lots, fire safety, and specific concerns about facility dangers to geriatric patients.

9. Falls (falls)—patient falls in the facility or in the parking lot.

10. General statements about patient safety (gen)—as stated.

11. Housekeeping (house)—errors related to housekeeping or the lack of adequate housekeeping.

12. Inexperience of personnel (inexp-lotx)- inexperience of hospital personnel that leads to incompetence and/or errors. Includes lack of appropriate training and concerns about provider competence, including contract personnel.

13. Infection control (infect)—nosocomial infection or other infection control issues.

14. Lack of supervision (lac sup)—lack of supervision of hospital personnel, to include inexperienced nurses, and medical interns and residents.

15. Lack of time (lot)—personnel not having enough time to adequately care for patients. Includes comments about excessive paperwork and taskings. Also includes remarks about lack of sufficient time with patients due to provider productivity requirements.

16. Medication errors (med)—errors related to medications, to include prescribing, dispensing, and administering medications.

17. Miscellaneous (misc)—miscellaneous comments that don't fit in the other codes and are not frequent comments.

18. Missed diagnosis (miss dx)—patient has not been diagnosed properly.

19. Needle sticks (needle)—as written. Also includes sharps injuries.

20. Not following instructions/orders (not follow). Includes not following SOPs.

21. Policy (pol)—primarily concerns about access/other problems attributed to TriCare.

22. Poor attitude of staff (poor att)—complacence or negative attitude. Rudeness to co-workers, patients. Includes apathy, poor work ethic, and low morale.

23. Positive statement about patient safety at the MTF (pos).

24. Patient confidentiality (pt con)—not safeguarding patient information.

25. Patient education (pt ed)—lack of appropriate patient education.

26. Patient identification (pt id)—errors made because of not properly identifying patients, specimens. Includes wrong site surgery sue to lack of appropriate identification of site.

27. Reporting of errors (report er)—lack of reporting of errors or problems with reporting of errors.

28. Restraint (restr)-errors related to use of restraints.

29. Scope of practice (s of p)—issues related to scope of practice. Misuse of physician extenders and technicians. Not adhering to practice standards.

30. Security (secur)—security of the MTF. Includes concerns about staff safety related to abusive/violent patients.

31. Specific to Facility (specif)—comment is unique to the MTF and does not fit wihin any other code.

32. Staffing (staf)—lack of appropriate staffing in the MTF.

33. Stress (stres)—stress experienced by hospital personnel leading to errors. Includes fatigue due to excessive hours worked by residents, other staff.

34. Taskings (task)—additional taskings that detract from direct patient care, including deployments.

35. Transfer or transport of patients (trans)—errors associated with the patient transfer/transport within and outside the MTF.

Appendix H

QUALITY ASSURANCE/RISK MANAGEMENT DOCUMENT

For use of this form, see AR 40-68; the proponent agency is the OTSG

Prepare this form according to instructions on the reverse side to document events which may have quality assurance/risk management implications involving patients, visitors or other persons.

1. Date of Event	2. Time of Event	3. Location	4. Age	5. Sex	6. ☐ INPATIENT ☐ OUTPATIENT ☐ EMERGENCY ROOM ☐ OTHER *(explain below)*	7. Attending Doctor

8. DIAGNOSIS(ES)	9. POST OP DAY

10. TYPE OF OCCURRENCE/INCIDENT *(check one only)*		11. CONDITION AFTER OCCURRENCE	
☐	Adverse Drug Reaction *(see instructions)*	☐ No Apparent Effect	Narrative *(optional)*:
☐	AMA/Walkout *(see instructions)*	☐ Minor Injury or Effect	
☐	Blood Transfusion *(see instructions)*	☐ Significant Injury or Effect	
☐	Equipment	☐ Death	
☐	Fall/Found on Floor *(Prescribed activity level:)*	☐ Other *(explain in narrative box)*	
☐	Laboratory	12. ACTION TAKEN	YES / NO
☐	Medication *(to include IV)*	Doctor Notified	☐ / ☐
☐	Pharmacy	Did Doctor see Patient	☐ / ☐
☐	Practice/Procedure Variance *(staff)*	X-Rays ordered/taken	☐ / ☐
☐	Property Loss or Damage	Reported to Supervisor/Department Chief	☐ / ☐
☐	Other *(explain)*	Laboratory tests ordered/taken	☐ / ☐
		Other *(explain in block 14)*	☐ / ☐

13. WITNESSES ☐ NONE ☐ Yes *(complete boxes below)*

a. Name(s)	b. Duty Section or Home Address	c. Phone

14. DESCRIPTION OF EVENT *(Concise, Factual, Objective Statement)*

If more space is needed, use a continuation sheet.

15. Name, Grade, Title of Individual Completing Form *(print)*	16. Signature	17. Date of Report

18. PATIENT ID PLATE OR PRINTED NAME AND SSN

The information placed on this form is confidential and privileged IAW 10 U.S.C. 1102.
UNAUTHORIZED DISCLOSURE CARRIES A $3,000 FINE.
DO NOT FILE OR REFER TO THIS FORM IN PATIENT RECORD. REPORT EVENT TO SUPERVISOR/DEPARTMENT CHIEF IMMEDIATELY.

FOR QA USE ONLY

19. Log Number _____

20. Further analysis indicated NO ☐ YES ☐

DA FORM 4106, MAR 90 — Previous edition is obsolete. — USAPPCV2.00

Appendix I

INSTRUCTIONS: UNUSUAL OCCURRENCE REPORTING
MEDCOM Test Form 731-R

PURPOSE:
The purpose of this document is to provide an effective method of documenting adverse events/incidents to Supervisors/Patient Safety Manager. The reported data are used to monitor, evaluate, and improve the quality and safety of patient services delivered.

SCOPE
Any MTF employee who discovers an actual or near miss occurrence or incident will complete the form. All actual or near miss occurrences should be reported, as they happen, to the immediate Supervisor and to the Patient Safety Manager as soon as possible. An occurrence/incident is defined as any actual or near miss event not consistent with patient care that either did or could result in an injury to a patient. Incident events do not necessarily involve patients, but may be the basis for a complaint, financial liability, and/or disciplinary action.

RESPONSIBILITY:
The individual who discovers any ACTUAL or NEAR MISS incident will initiate the document and gather as much data as possible on the form prior to forwarding it to the Supervisor and/or Patient Safety Manager.

DIRECTIONS FOR COMPLETION:

- **Form Design:**
  1. MEDCOM Form 731-R is composed of 4 pages.
  2. Page 2 includes the core information that must be completed for any event whether NEAR MISS or ACTUAL. The entire page must be filled out where appropriate.
     - To be completed for all ACTUAL or NEAR MISS events.
     - Complete all boxes that apply.
       - *Diagnosis:* Provide primary and secondary diagnosis as indicated in patient's record and any other contributing diagnoses that may relate to the event/incident.
       - *Nursing Care Hours*: Enter Unit Total Nursing Care Hours at the time of the event
       - *Patient Acuity Level*: Enter patient acuity level at the time of event.
     - Section IV: Select all the actions implemented after the event occurred
  3. Depending on the type of event, additional sections must be filled out on pages 3 and 4.
  4. Page 3 is comprised of multiple sections that should be completed where applicable. Specifically the employee data should be completed for any type of incident.
  5. Page 4 will address medication and fall related events only.
  6. Page 3—Complete the appropriate sections based on the type of event. Sections XII, XIII, and XIV employee data should be completed for any type of event, if available.
  7. Pages 4 and 5 will be completed for any medication or fall related event.
  8. Although optional, it is highly encouraged to obtain the name of the reporting individual in order to obtain additional and/or clarify information.

ROUTING OF FORM:
The document should be forwarded through appropriate local channels but at a minimum should be completed and staffed through the Supervisor/Department Chief within 24 hours of discovery of the event or on the first duty day following a weekend or holiday. The manager/supervisor will review the DA Form 4106, add additional relevant information, and forward it to the MTF Patient Safety Manager within 24 hours of having received the form.

UNUSUAL OCCURRENCE REPORT

For use of this form see MEDCOM Cir XX-XX

DATE of EVENT:

1. MTF:	2. Time of Event:	3. Census:	4. Nursing Care Hours:	5. Patient Acuity Level: (I - VI)

☐ Patient ☐ Staff ☐ Visitor Name (print clearly) _____

5. Visitor Address: _____ Daytime Phone: _____

6. Diagnosis: _____ ☐ Male ☐ Female Age _____

7. Allergies: _____

SECTION I - LOCATION/DESCRIPTION of EVENT

☐ Inpatient ☐ Outpatient ☐ Ward/Unit: _____ ☐ Clinic: _____ ☐ ER: (specify location) _____ ☐ Other: _____

Describe the event: (Give specific details):

SECTION II - ACTUAL STAFF on DUTY at TIME of EVENT

RN: _____ LPN/91C: _____ NA/91B/91W: _____ Pharmacist: _____ Physician: _____ Tech: _____

SECTION III - TYPE of EVENT *(Select all that apply)*

☐ **Actual** ☐ **Near Miss/Close Call** *(Select one)*

- ☐ AMA/Left Without Being Seen
- ☐ Adverse Drug Related Event
- ☐ Assault
  - ☐ Patient to Patient ☐ Staff to Staff
  - ☐ Patient to Staff ☐ Visitor to Staff
  - ☐ Patient to Visitor ☐ Visitor to Visitor
- ☐ Blood Products Related (go to Section VI)
- ☐ Complaint - ☐ Patient ☐ Visitor
- ☐ Delay in ☐ Treatment ☐ Diagnosis ☐ Transfer
- ☐ Equipment/Supply Related (go to Section VIII)
- ☐ Environment of Care (go to Section VII)
- ☐ Exposure to Blood/Body Fluids
- ☐ Fall (go to Section XVIII)
- ☐ Infant Abduction ☐ Discharge to Wrong Family
- ☐ Informed Consent
- ☐ Laboratory Related (go to Section IX)
- ☐ Medication Related (go to Section XV)
- ☐ Needlestick/Sharps
- ☐ Obstetrics Related (go to Section X)
- ☐ Operative and Other Procedure Related (go to Section XI)
- ☐ Patient Injury in Restraints
- ☐ Rape
- ☐ Suicide in a 24hr Care Facility

SECTION IV - ACTION(S) IMPLEMENTED *(Select all that apply)*

- ☐ Admission or Readmission
- ☐ Airway Established/Patient Ventilated
- ☐ Antidote Administered
- ☐ Cardiac Defibrillation Performed
- ☐ CPR Administered
- ☐ Discontinued ☐ Treatment ☐ Drug ☐ Blood
- ☐ Equipment /device Taken Out of Service
- ☐ Event Documented in Medical Record
- ☐ Family/Guardian Informed of Event
- ☐ Laboratory Test Ordered
- ☐ Lab Analysis Repeated, Original Specimen
- ☐ Lab Analysis Reordered, New Specimen
- ☐ Medical Treatment Delayed
- ☐ Medical Treatment Terminated
- ☐ Narcotic Antagonist Administered
- ☐ Observation Initiated/Increased
- ☐ Oxygen Administered
- ☐ Patient Informed of Event
- ☐ Patient Return Appointment Required
- ☐ Physician Notified
- ☐ Physician Examined Patient
- ☐ Reported to Supervisor/Department Chief/AOD
- ☐ Safety Notified (Hospital)
- ☐ Sent to ER for Evaluation
- ☐ Surgery ☐ Delayed ☐ Cancelled
- ☐ Surgery Performed
- ☐ Transferred to Higher Level Care
- ☐ Vital Signs Monitoring Initiated or Increased
- ☐ X-rays/MRI/Other Diagnostic Test Performed
- ☐ Other _____

SECTION V - PATIENT OUTCOME

- ☐ No Apparent Effect or Injury
- ☐ **Minor Effect** - No increased length of stay or level of care
- ☐ **Moderate** - Increased length of stay or higher level of care for less than 3 days
- ☐ **Major** - Increased length of stay/level of care of 3 days or more; surgical intervention; disfigurement; permanent lessening of body functioning
- ☐ **Catastrophic** - Death or permanent loss of function, suicide, rape, hemolytic transfusion reaction, surger or wrong patient, infant abduction/discharge to wrong family.

PATIENT'S IDENTIFICATION *(For typed or written entries give: Name - last, first, middle; grade; FMP/SSN; hospital registration number)*

The Information placed on this form is confidential and privileged IAW 10 U.S.C. 1102.
UNAUTHORIZED DISCLOSURE CARRIES A $3,000 FINE.
DO NOT FILE OR REFER TO THIS FORM IN PATIENT RECORD. REPORT EVENT TO SUPERVISOR/DEPARTMENT CHIEF IMMEDIATELY.

Log # _____
(For PSM Use Only)

SECTION VI - BLOOD PRODUCTS/BLOOD TRANSFUSION REACTION RELATED

	YES	NO
1. Was it documented on the SF518?		
2. Was the transfusion stopped immediately?		
3. Was the Blood Bank notified?		
4. Was the Blood Bank given a copy of the SF518?		
5. Was transfusion reaction work-up initiated?		
6. Was there a hemolytic reaction?		

SECTION VII - ENVIRONMENT OF CARE

- ☐ Fire
- ☐ Hazardous Material
- ☐ Security
- ☐ Medical Gas
- ☐ Utilities (electrical, plumbing, etc)
- ☐ Other _____

SECTION VIII - EQUIPMENT RELATED *(Check all that apply)*:

Product/device:

Name: _____

Serial #: _____

Manufacturer: _____

- ☐ Equipment Failure
- ☐ Equipment Unavailable
- ☐ Incorrect Set-up
- ☐ Improper Use
- ☐ Malfunction/Defect
- ☐ Wrong Equipment
- ☐ Other _____

Were device and accessories taken out of service? ☐ Yes ☐ No If yes, where is equipment stored?

SECTION IX - LABORATORY RELATED *(Check all that apply)*:

- ☐ Improper Collection Technique
- ☐ Incorrect Container/Tube Received
- ☐ Order Entry Error
- ☐ Order Missed
- ☐ Patient ID Error
- ☐ Result Inaccurate
- ☐ Wrong Treatment Information Given to Lab
- ☐ Results Not Interpretable
- ☐ Specimen Handling Error
- ☐ Specimen ID Error
- ☐ Specimen Processing Delayed
- ☐ Testing/Results Delay
- ☐ Unnecessary Testing Performed
- ☐ Other: _____

SECTION X - OBSTETRICS RELATED

- ☐ Apgar < 6 after 5 minutes
- ☐ Fetal Distress/Injury
- ☐ Maternal Death
- ☐ Monitoring
- ☐ Newborn Birth Trauma
- ☐ Premature Labor
- ☐ Operative Delivery Complication
- ☐ Other: _____

SECTION XI - OPERATIVE and OTHER PROCEDURE RELATED

- ☐ Adverse Reaction to Anesthesia
- ☐ Break in Sterile Technique
- ☐ Consent Incomplete/Incorrect
- ☐ Incorrect Instrument Count
- ☐ Incorrect Needle Count
- ☐ Incorrect Sponge Count
- ☐ Procedure Cancelled
- ☐ Return to OR within 24 Hours
- ☐ Trauma to Healthy Tissue
- ☐ Unexpected Complication
- ☐ Unexpected Delay
- ☐ Wrong Site Surgery
  - ☐ Wrong Side
  - ☐ Wrong Level
  - ☐ Wrong Body Part
- ☐ Wrong Patient
- ☐ Wrong Procedure Performed
- ☐ Improper Prep
- ☐ Incorrect Technique
- ☐ Omission
- ☐ Other: _____

SECTION XII - EMPLOYEE DATA *(Enter number from list below.)*

Level of Staff that _____ made error error _____ discovered error _____ involved in error

1. Administrative/MRT/Clerk
2. Dietary/Food Service
3. Housekeeping
4. Laboratory Tech
5. LPN/91Ct
6. Logistics/MED Maintenance
7. NA/91B/91W
8. Occupational Therapist
9. Phlebotomist
10. Physician Assistant
11. Pharmacy Tech
12. Pharmacist
13. Physician/Pathologist/Radiologist
14. Physical Therapist
15. Radiology Tech
16. Resident Intern
17. Respiratory Therapist
18. RN
19. Other

SECTION XIII - STATUS of STAFF that made Error

- ☐ Permanent Staff
- ☐ Borrowed Staff/Float
- ☐ Reservist
- ☐ Student/Training Status
- ☐ Orientee
- ☐ Contract/Agency
- ☐ Red Cross Volunteer
- ☐ Part Time
- ☐ Full Time
- ☐ Other _____

Work Experience

- ☐ Less Than 1 Year
- ☐ Greater Than 1 Year

Hours worked prior to event: _____

Hours worked in succession: _____

SECTION XIV - DEPARTMENTS INVOLVED

- ☐ Ambulatory Care
- ☐ Behavioral/Mental Health
- ☐ Dental
- ☐ Emergency Care
- ☐ Information Management
- ☐ Laboratory
- ☐ Medicine
  - Subspecialty _____
- ☐ Logistics (Maintenance, Grounds, Housekeeping)
- ☐ Obstetrics
- ☐ Pediatrics
- ☐ Pharmacy
- ☐ Radiology
- ☐ Surgery
  - Subspecialty _____
- ☐ Other/s _____

SECTION XV - MEDICATION(S) INVOLVED

Prescribed Medication	Dose/Frequency	Manufacturer	Brand Name	Generic Name
Medication Administered	**Dose/Frequency**	**Manufacturer**	**Brand Name**	**Generic Name**

Where in the medication process did error occur?

☐ Prescribing ☐ Dispensing ☐ Administering ☐ Documenting ☐ Monitoring

PART A - TYPE OF MEDICATION ERROR *(Check all that apply)*

PRESCRIBING

- ☐ Wrong Drug Ordered
- ☐ Wrong Dose
- ☐ Wrong Strength/Concentration
- ☐ Wrong Patient

DOCUMENTING (MEDICATION NOT ADMINISTRATION RECORD = MAR)

- ☐ Medication not on MAR
- ☐ Medication discontinued, still on MAR
- ☐ Duplicate order on MAR
- ☐ Incorrect drug on MAR
- ☐ Incorrect dose on MAR

DISPENSING

- ☐ Wrong Drug Dispensed ☐ Dose Administered
- ☐ Wrong Dose not Dispensed (Missed)
- ☐ Wrong Extra Dose Dispensed
- ☐ Wrong Calculation
- ☐ Wrong Drug in Pyxis
- ☐ Wrong Preparation

ALLERGY or INTERACTION*

- ☐ Drug-Drug Interaction
- ☐ Drug-Food Interaction
- ☐ Patient Allergic to Medication and Medication ☐ Given
- ☐ Allergic Reaction in Patient with unknown Drug Allergy

Fill out FDA Form IAW local policy

ADMINISTERING

- ☐ Wrong Route of Administration
- ☐ Wrong Drug Administered
- ☐ Wrong Rate of Administration
- ☐ Wrong Duration of Therapy
- ☐ Wrong Time Scheduled
- ☐ Wrong Time Given
- ☐ Wrong Patient
- ☐ Wrong Administration Technique
- ☐ Wrong Dose Administered

OTHER

- ☐ Therapeutic Duplication
- ☐ Medication found on Dietary Tray
- ☐ Illegible Order, Physician contacted
- ☐ Expired Drug Administrered
- ☐ Reconciliation Error
- ☐ Other _____

PART B - DRUG CLASSIFICATION

- ☐ Analgesics
- ☐ Anesthetics
- ☐ Antibiotic
- ☐ Anticoagulant
- ☐ Anticonvulsant
- ☐ Antihypertensive
- ☐ Blood Product
- ☐ Cardiac
- ☐ Chemotherapy
- ☐ Diuretic
- ☐ Electrolyte
- ☐ Hyperalimentation
- ☐ Immune Serum/Vaccine
- ☐ Insulin
- ☐ Muscle Relaxant
- ☐ Narcotic
- ☐ Psychotropic
- ☐ Renal
- ☐ Repiratory
- ☐ Sedative/Hypnotic
- ☐ Thrombolytic
- ☐ Other _____

SECTION XVII - FALLS (Complete this Section only if Event is a Fall) *(Check all that apply)*

PART A - ENVIRONMENTAL FACTORS

	YES	NO	N/A
1. Bed in lowest position			
2. Bedrails in up position			
3. Necessary items placed within reach of patient			
4. Floor was dry			
5. Hallways/floors free of obstacles			
6. Adequate footwear was in use (non-slip soles)			
7. Patient/Family oriented to falls protocol			
8. Adequate patient or family/other education			
9. Patient on Falls Protocol			

10. Other _____

SECTION XVIII - FALLS (Complete this Section only if Event is a Fall) *(Check all that apply)*

PART B - FALL RELATED FACTORS

TYPE	PRIOR CONDITION	ACTIVITY LEVEL	INFLUENCING FACTORS
☐ While Ambulating	☐ Alert/Oriented	☐ Bedrest	☐ Medication
☐ Found on Floor	☐ Agitated	☐ Up with Assistance	☐ Environmental
☐ Fall from Bed/Chair	☐ Confused	☐ Up with Mechanical Aid	☐ Equipment
☐ Fall from Equipment	☐ ETOH Odor	☐ Up with Bathroom Privileges	☐ Other _____
☐ Building/Ground	☐ Sedated	☐ Up Ad Lib	
☐ Other _____	☐ Other _____	☐ Restraints	
		☐ Other _____	

THANK YOU FOR COMPLETING THIS FORM

May we contact you for additional information? ☐ Yes ☐ No

Name of person completing report: _____

Your Title: _____

Telephone: (W) _____ (FAX) _____

E-Mail Address (If available): _____